



International Society for Prosthetics and Orthotics

**REPORT OF A CONSENSUS CONFERENCE
ON THE ORTHOTIC MANAGEMENT
OF STROKE PATIENTS**

**Edited by
Elizabeth Condie**

**Associate editors
James Campbell
Juan Martina**

**Held at:
Avegoor Conference Centre
Ellecom
The Netherlands
21st - 26th September, 2003**



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Stroke Definition - WHO Bulletin, 1976

" A stroke is a clinical syndrome characterised by rapidly developing clinical symptoms and/or signs of focal, and at times global (applied to patients in deep coma and those with subarachnoid haemorrhage), loss of cerebral function, with symptoms lasting more than 24 hours or leading to death, with no apparent cause other than that of vascular origin."



CONFERENCE PARTICIPANTS

ACKNOWLEDGEMENTS

The Organising Committee wishes to express its sincere gratitude to Linda Gilmour for invaluable secretarial support given during the development and report writing phases of the Conference and to Anne Slater for preparing the manuscript for printing.

It also wishes to acknowledge the enormous task undertaken by Heather Smart and colleagues at RECAL Information Services, University of Strathclyde in searching for and photocopying some 2,700 Scientific papers which formed the foundations for the Conference.

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PROGRAMME

KEY

R - Key Review Paper

S - State of the Art Paper

Sunday 20 September

18.00 - 20.00 Welcome cocktails. Introductory remarks J.Martina
 20.00 Dinner

Monday 22 September

08.30 - 09.00	Introduction and Briefing	E.Condie	
09.00 - 09.50	Stroke- Understanding the problem (Epidemiology, incidence and prevalence)	T.Olsen	S1
09.50 - 10.40	Clinical and functional effects of stroke.	R.Wagenaar	S2
10.40 - 11.10	Coffee		
11.10 - 11.55	Understanding tone and spasticity.	J.Becher	S3
11.55 - 12.40	Biomechanics of lower limb function and gait.	S. Gard	S4
12.40 - 13.45	Lunch		
13.45 - 14.30	Current situation in lower limb orthotics.	D.Blocka	S5
14.30 - 15.15	Establishing a scientific basis for orthotic management.	J.Campbell	R1
15.15 - 15.25	Questions.		
15.25 - 15.45	Tea		
15.45 - 16.30	AFO and FO - non articulated.	R.Bowers	R2
16.30 - 17.15	AFO - articulated.	D.Hoy/A.Karas	R3
17.15 - 17.30	Questions		

Tuesday 23 September

08.30 - 09.15	Syndicate A (R1,R2, R3)		
09.15 - 09.45	General Discussion		
09.45 - 10.15	Coffee		
10.15 - 11.05	Physiotherapy lower limb	R.Bohannon	R4
11.05 - 11.15	Questions		
11.15 - 11.55	F.E.S. lower limb	J.Buurke	R5
11.55 - 12.05	Questions		
12.05 - 12.45	Pharmacological management, lower limb	G.Francisco	R6
12.45 - 12.55	Questions		
12.55 - 14.00	Lunch		
14.00 - 14.45	Syndicate B (R4, R5, R6)		
14.45 - 15.20	General Discussion		
15.20 - 15.40	Tea		
15.40 - 16.20	Surgery, lower limb	J.Patrick/A.Jain	R7
16.20 - 16.30	Questions		
16.30 - 17.00	Cochrane systematic reviews: Protocol "Orthotic devices for abnormal posture after stroke or non-progressive cerebral causes of spasticity"	R.Kent	S6

Wednesday 24 September

08.30 - 09.10	Orthotic management of hip and knee.	D.Fish	R8
09.10 - 09.20	Questions.		
09.20 - 09.50	Syndicate C (R7, R8)		
09.50 - 10.15	General discussion.		
10.15 - 10.45	Coffee		
10.45 - 11.15	Biomechanics of upper limb.	T.Dibello/D.Plettenburg	S7
11.15 - 12.05	Physiotherapy management of upper limb.	M. Smith/P. Van Vliet	R9
12.05 - 12.20	Questions.		
12.20 - 13.20	Lunch		
13.20 - 14.00	Occupational Therapy for upper limb.	J.Ranka/A.Drummond	R10
14.00 - 14.10	Questions.		
14.10 - 14.50	Pharmacology, upper limb.	A.Yelnik	R11
14.50 - 15.00	Questions.		
15.00 - 15.30	Tea		
15.30 - 16.10	FES and upper limb.	J.Chae	R12
16.10 - 16.20	Questions.		
16.10 - 16.50	Surgery and upper limb.	M.A.Keenan	R13
16.50 - 17.00	Questions.		

Thursday 25 September

08.30 - 09.10	Orthotic management of upper limb.	N. Parent	R14
09.10 - 09.20	Questions.		
09.20 - 10.05	Syndicate D (R9,10,11,12,13,14)		
10.05 - 10.35	Coffee		
10.35 - 11.05	General discussion.		
11.05 - 11.45	Service delivery issues.	D.Condie	R15
11.45 - 11.55	Questions		
11.55 - 12.30	When to prescribe orthoses?	M.Hodge	R16
12.30 - 13.30	Lunch		
13.30 - 14.15	Score scales and outcome measures.	V.Pomeroy/S.Lennon	R17
14.15 - 14.25	Questions.		
14.25 - 15.10	Current research in orthotics.	C.Morris	R18
15.10 - 15.20	Questions.		
15.20 - 15.50	Tea		
15.50 - 16.35	Syndicate E (R15,16,17,18)		
16.35 - 17.05	General discussion.		
17.05 - 18.00	Review of Conference. Agree consensus and content of report.	J.Martina/ E.Condie/J.Campbell	
19.00	Reception and Conference Dinner		

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REPORT OF A CONSENSUS CONFERENCE ON THE ORTHOTIC MANAGEMENT OF STROKE PATIENTS

BACKGROUND

The use of orthoses in the management of patients with stroke has been recognised as a treatment option for many years. There is, however, widespread variation in the nature of orthotic intervention, not just between countries but also between centres at a local level.

In particular, there is no agreed 'best practice' in terms of selection of patients for orthotic fitting, design of the orthosis, and timing of orthotic intervention. Further, evidence of the effectiveness of orthoses, both for the upper and lower limb is scanty and the decision as to whether or not to use an orthosis, when, and of which design is normally based on clinical experience and practitioner preference rather than scientific evidence. There is no complete understanding of how orthotic management relates to other treatment modalities such as physio and occupational therapy, FES, pharmacology and surgery.

I became particularly aware of these issues when, as co-ordinator of the short, post graduate course programme for health care professionals at the National Centre for Training and Education in Prosthetics and Orthotics, my colleagues and I were regularly challenged by course participants to defend our teaching that the use of orthoses for selected stroke patients was a "good thing".

I therefore approached the Executive Board of ISPO in 2001 with the proposal that a "Consensus Conference" on the subject of the 'Orthotic Management of Stroke Patients' be convened. A justification for this type of conference is to be found in several international publications, and a key document published by the NHS Health Technology Assessment Programme (1) states that "Consensus methods are used to develop clinical guidelines (good practice) which define key aspects of quality health care, particularly appropriate indications for interventions". ISPO has organised five such conferences over the past 14 years and as a multidisciplinary, international society is a very appropriate organisation to undertake such a project.

PREVIOUS CONSENSUS CONFERENCES

DATE (YEAR)

- 1990 - Report of a Consensus Conference on Amputation Surgery
- 1994 - Lower Limb Orthotic Management of Cerebral Palsy
- 1995 - Appropriate Prosthetic Technology for Developing Countries
- 1997 - Consensus Conference on Poliomyelitis : Consensus Statements and Syndicate Reports
- 2000 - Appropriate Prosthetic and Orthotic Technology for Low Income Countries.

The Board agreed to this proposal and a small organising committee was established comprising Jim Campbell, a prosthetist/orthotist from Scotland currently working in North America, Juan Martina, a doctor in rehabilitation medicine from Holland who as a member of the ISPO Executive Board would act as Chairman, and myself.

SCOPE

At our first planning meeting in April 2002, the **Scope** of the conference was decided. It would include the biomechanical design of, assessment for and prescription of orthoses for both the upper and lower limb. It would exclude the immediate medical management of stroke patients and would deal, primarily, with the rehabilitation phase, which was defined as beginning as soon as the patient is medically stable.

The rehabilitation of stroke patients requires an integrated system of care from many specialities, and it was therefore felt important to include consideration of the following treatment options as they relate to orthotic management;

- medical and pharmacological management
- surgery
- therapy (P.T. and O.T.)
- functional electrical stimulation

OBJECTIVES

These were to

- Trace, review and rank all the international literature relevant to the scope of the conference.
- Identify gaps in the literature where scientific evidence was weak or absent
- Discuss key questions arising from this review
- By means of expert group discussions, achieve consensus on 'best practice' in the absence of any scientific evidence
- Document and report the recommendations of conference
- Encourage the dissemination and implementation of the recommendations internationally

METHOD

A. IN ADVANCE

A budget was agreed with the ISPO Executive Board, which would allow 45 experts in the field (not necessarily ISPO members) to attend with their travel and hotel costs being paid in full.

Participants were selected in almost equal numbers from the following professions : orthotics, physio/occupational therapy, medicine and surgery, clinical engineering/biomedical sciences. A total of 14 countries were represented. Each participant was allocated the task of 'key reviewer', 'state of the art presenter' or 'expert discussant'.

All would be expected to actively participate in the group discussions throughout the week. There would be no observers.

A comprehensive literature search starting from the year 1990 was conducted by Heather Smart (Information Officer at the NCTEPO) and colleagues using the RECAL database, with a supplementary search of Medline, Embase, CDSR, CCTR, ACP Journal Club, Dare and Premedline conducted by Glasgow Royal Infirmary Information Service. A total of approximately 2700 articles were identified.

A preliminary scan was conducted by the organising committee to remove any wholly inappropriate paper after which photocopied sets of papers were allocated and sent to each "key reviewer". They were asked to rank the evidence contained in each paper according to a recognised system of critical appraisal described by Greenhaugh in 1997(2) (Table1). The appraised papers were then to be graded and grouped as falling into categories A, B, C or * as defined by Shekelle et al (3) (Table 2). Key reviewers were invited to include any appropriate article known to them, but not provided by the committee, in order to achieve as comprehensive a review as possible.

The meeting was held at the Avegoor Conference Centre on the outskirts of Arnhem, Holland. This venue, a very pleasant and comfortable hotel, was in keeping with the HTA guidelines for consensus conferences, which state that "a comfortable environment for meetings is likely to be preferred by participants and to be conducive to discussion".

LEVEL OF EVIDENCE	
Rating of Study Design	Type of Study
I	Systematic Review and or meta analysis (where statistical techniques are used to pool the results of included studies)
IIa	Randomized Controlled Trial (with definitive results that do not overlap the threshold clinically significant effect)
IIb	Randomized Controlled Trial (with non definitive results i.e. a point estimated that suggests a clinically effective effect with confidence intervals that overlap the threshold clinically significant effect)
III	Cohort Studies (Two or more groups are selected on the basis of differences in their exposure to a particular agent and followed up to see how many in each group developed a particular disease or other outcome)
IV	Case Control Studies (Patients with a particular disease or condition are identified and matched with controls, like cohort studies case control studies are generally concerned with the etiology of a disease)
V	Cross Sectional Survey (Data are collected at a single time point but may refer retrospectively to health experiences in the past)
VI	Case Reports
VII	Expert Opinion

Table 1

GRADE OF RECOMMENDATION	
A	Directly based on Category I or IIa evidence, at least one meta analysis.
B	Directly based on Category IIb, III or IV evidence or extrapolated from Category I, II, III or IV,
C	Directly based on Category V or VI evidence or extrapolated from Category, I, II, III or IV.
*	Good practice point, recommended best practice based upon clinical experience of the guideline development group.

Table 2

B. AT CONFERENCE

Seven ‘state of the art’ presenters provided an overview of current practices in specified topic areas.

These were followed by eighteen ‘key review papers’, which were based on a structured review and appraisal of the available literature as previously described.

Each reviewer, along with the session chairman and scribe, then met with members of the organising group to agree upon areas where there was no evidence or agreement in the literature, or where the evidence fell below Grade B as defined by Shekelle et al (3). These formed the basis for subsequent ‘syndicate sessions’ where all participants worked in pre-organised small groups, each with a chairman and scribe, to formulate recommendations based on the expert opinion of the syndicate.

These recommendations were then brought back to the entire group for general discussion and ‘conclusions and recommendations of conference’ were agreed and are reported in this document.

C. AFTER CONFERENCE

All presenters were given the opportunity to revise or amend their paper prior to publication and were asked to submit the final version for preparation for publication within 3 months.

The conclusions and recommendations were drafted by myself and distributed to all participants for comment and approval before publication.

The report can therefore be said to represent the agreed views of an international group, expert in the field of stroke management, and in the true spirit of consensus.

The Conference, and its preparation, demanded a very significant amount of work on the part of all participants, including my colleagues on the Organising Committee. That the conference achieved five out of six of its original objectives was entirely due to the commitment and hard work of each and every one of those involved.

The sixth objective, to disseminate and implement the recommendations, will require further efforts on the part not only of the conference attendees, but members of ISPO worldwide. It is my fervent hope that these recommendations **will** result in improvements to the care of stroke patients, and it is only then that we can claim to have fully accomplished our aim.

Elizabeth Condie
January 2004

GENERAL RECOMMENDATIONS

The following recommendations, (1-15) were unanimously agreed by conference and relate to all aspects of the orthotic management of stroke patients. They are not necessarily extrapolated from the literature reviews but are rather a series of good practice points.

Grade of Recommendation

- | | |
|--|---|
| <p>1. The use of orthoses, both for the lower and upper limb, should be considered in the management of patients with stroke.</p> | C |
| <p>2. The indications for the use of appropriate orthoses should be included in the education and training of all professional staff involved in the rehabilitation of stroke patients. This may take place at under-or-post-graduate level.</p> | * |
| <p>3. Qualified orthotists should be included as part of a stroke rehabilitation team and should contribute to assessment for and prescription of orthoses. They should be specifically responsible for manufacture and delivery of orthotic devices with the exception of circumstances detailed at point 4 below. Conference agreed with the statement made in an earlier ISPO consensus conference report on the Lower Limb Orthotic Management of Cerebral Palsy (4) that "Orthotic Care cannot effectively be provided in isolation".</p> | C |
| <p>4. Conference recognised, however, that a qualified orthotist may not be available at all times; reasons include:</p> <ul style="list-style-type: none"> • remote geographic regional clinic without full clinic team • inadequately resourced service • "visiting" orthotists attending intermittent clinics <p>In these circumstances, it was agreed that other professional staff with specific post-registration training may provide temporary orthoses including low temperature, thermoplastic, upper limb and hand orthoses used in combination with occupational and/or physiotherapy.</p> | * |
| <p>5. The scientific literature on the orthotic management of stroke is generally poor both in terms of quality and quantity with very few papers reviewed reaching Grades A or B as described by Shekele et al (3). Conference therefore recommended that academic institutions, researchers and clinicians make strenuous efforts to increase the body of evidence by means of good quality, scientific research in this area. Well-controlled, multi-centre trials involving large numbers of patients are urgently needed.</p> <p><i>N.B Conference recognised that many health care professionals are not skilled in experimental design and may lack research experience. Papers by Chris Morris and Robert Wagenaar, both conference participants, were therefore commissioned by conference entitled, respectively, "Glossary of Research Terms" and "Guidelines for Stroke Rehabilitation Research". These are included at Appendix A and Appendix B.</i></p> | * |
| <p>6. Many of the recommendations and conclusions in this report are graded as *- 'good practice points'. This means that there is a lack of scientific evidence in support of these statements. Conference therefore recommends that these 'good practice points' are used as a basis for priority research in this field.</p> | * |
| <p>7. It was apparent from the literature reviews and from discussions at conference that terminology used both within and between professional groups is inconsistent. This can relate to both orthotic components (e.g. "non-articulated" or "solid ankle" AFO) and to patient description (e.g. "varus", "supinated" or "inverted" foot position). Ambiguous terms such as "dynamic" are commonly used. The correct classification of spasticity is not well known nor totally accepted. Where International, standard terminology exists as, for example, contained in ISO documents (4,5,6,7), this should be adopted and implemented with immediate effect. This may not, however adequately describe all contemporary orthoses and conference therefore recommends that an International Working Group is established as soon as possible to investigate the issue of orthotic terminology and agree standard definitions. Conference suggested that ISPO is an ideal organisation to implement this recommendation.</p> | * |

**Grade of
Recommendation**

8. In many of the reviewed papers, the research methodology is sound however the description of the orthotic device is incomplete and, at times, absent. This greatly reduces the validity of the research project as it is impossible to judge whether or not the biomechanical design of the orthosis is appropriate. Further, rates of, and reasons for, rejection of the orthosis by the experimental group are frequently missing. Conference therefore **recommends** that the biomechanical design, materials and components of orthoses which are the subject of research should be clearly stated. Rejection rates, and reasons for rejection, **should** also be listed. *
9. The question of *who* should be responsible for the written prescription for an orthosis was posed. Traditionally, a doctor has fulfilled this role, however it was recognised that not all doctors have the appropriate knowledge or experience. Further, the writing of a *prescription* for an orthosis should not be necessary given the professional training of orthotists and it was **agreed** that *referral* is a more accurate term. The conclusion was therefore that the orthotic referral **should** be written by an appropriately trained doctor, orthotist or therapist, or any combination of these, depending on local circumstances. *
10. The orthotic *referral* **should** include (not in any particular order)
 - Diagnosis and relevant history, including adjunct treatment
 - Precautions (e.g. diabetic neuropathy, decreased sensation)
 - Musculoskeletal impairments, including a statement as to whether a joint deformity/contracture is fixed or not. *
 - Gait analysis details (instrumented if available and/or visual) if the patient is mobile
 - Functional limitations
 - Result of a validated scale of status, impairment or measure of severity
 - Clinical objectives and functional requirements
 - Broad category of orthosis (AFO/KAFO)
11. The orthotic *specification or description* **should** be written by an orthotist and include:
 - Description of the mechanical force system required, including a detailed description of any joint or articulation
 - The alignment of the orthosis, e.g. the ankle angle of a non-articulating AFO or range of motion at the orthotic ankle joint. *
 - Components and materials, including types of closure e.g. straps, buckles or Velcro.
12. The design of all orthotic devices **should** be based upon sound biomechanical principles. *
13. Conference **recommended** that during the period of recovery, regular monitoring of gait and upper extremity function is **essential** to inform the adjustment of the design of the orthosis as necessary. *
14. Conference **agreed** that the maintenance of complete records of any treatment provided is an integral part of the clinical duties of the orthotist like any other health care professional. *
15. The *dissemination and implementation* of this report and the recommendations contained within it are crucial if the quality of orthotic care for stroke patients is to be influenced. Conference therefore **recommends** that a 'task officer' be appointed to take responsibility for these matters and for the organisation of interdisciplinary courses based on the content of this report and using recognised experts from each discipline. *

CONCLUSIONS AND RECOMMENDATIONS ARISING FROM SYNDICATE AND GENERAL DISCUSSION SESSIONS

In view of the volume of the material covered by the reviewers, this section primarily lists the conclusions and recommendations agreed by conference during the syndicate and discussions sessions. A comprehensive list of detailed recommendations, duly graded, may be found in the key review papers themselves.

The undernoted recommendations (16-20) resulted from the Syndicate A and General Discussions of Review Papers R1 (Establishing a scientific basis for orthotic management), R2 (AFO and FO, non-articulated) and R3 (AFO, articulated).

	Grade of Recommendation
16. Indications for a <i>non-articulated AFO</i> were agreed as follows:	
• Poor balance, instability in stance	*
• Inability to transfer weight onto affected leg in stance	C
• Moderate to severe foot abnormality; equinus, valgus or varus, or a combination	C
• Moderate to severe hypertonicity	*
• As above, but with mild recurvatum or instability of the knee	C
• To improve walking speed and cadence	C
17. Indications for an <i>articulated AFO</i> were agreed as follows:	
• Dorsiflexor weakness only	*
• Where passive or active range of dorsiflexion is present	*
• Where dorsiflexion is needed for sit-to-stand or stair climbing	*
• To control knee flexion instability only, articulated AFO with dorsiflexion stop	*
• To control recurvatum only, articulated AFO with plantar flexion stop	*
• To improve walking speed and cadence	B
18. Conference agreed that a custom-made <i>Posterior Leaf Spring (PLS)</i> ankle foot orthosis falls neither into the "articulated" nor "non-articulated" AFO category, and for the purposes of this report is therefore referred to as a <i>flexible AFO</i> . Indications for its use were agreed as follows:	
• Isolated dorsiflexor weakness	*
• No significant problem with tone	*
• No significant medio-lateral instability	*
• No need for orthotic influence on the knee or hip.	*
19. Conference considered the use of prefabricated, "off-the-shelf" AFO's and recommended that their use should be limited to the following situations only:	
• As a temporary, evaluation orthosis.	*
• where there is a need for early mobilisation before a custom orthosis can be provided	*
<i>N.B. Conference does not recommend an off-the-shelf orthosis in the presence of problematic increased tone in plantar or dorsiflexor muscles, or in the presence of significant medio-lateral instability.</i>	*
20. Conference considered the question of providing an AFO for use in weight bearing as soon as the patient is medically stable. There is no evidence in the literature in support of this practice however conference agreed that the following benefits can be extrapolated from the literature on the orthotic management of cerebral palsy:	
- Encourages balanced standing	*
- Provides ankle stability	*
- Promotes postural alignment	*
- Maintains range of motion at the ankle	*
- Supports early mobilisation	*

The undernoted recommendations (20-30) resulted from the Syndicate B and General Discussions of Review Papers R4 (Physiotherapy, lower limb), R5 (FES, lower limb) and R5 (Pharmacological management, lower limb).

	Grade of Recommendation
21. Conference recommended that orthoses can be used in combination with physiotherapy for minimising the development of contractures/deformities in the early or acute phase. <i>N.B. Conference noted the differences in the interpretation of "early", "acute", "chronic", and "late" phases with regard to rehabilitation. It therefore recommends that there should be an agreement of this terminology by all professional groups involved in this field.</i>	*
22. Strength training bouts of adequate volume and duration will result in increases in strength (A), and can result in increase in function (B), beyond those realised in the absence of such training.	A, B
23. Adequate volumes of aerobic exercise (cycle or treadmill), alone or in combination with other exercise, will result in increased aerobic capacity.	A
24. Non ambulating and poorly ambulating patients participating in adequate volumes of treadmill training improve more in gait than similar patients not so treated.	B
25. In the presence of "dropped foot", FES of the dorsiflexor muscles has a positive effect on walking speed and the Physiological Cost Index (PCI)	B
26. During the period of recovery, regular monitoring of gait is needed to modify the biomechanical design of the orthosis as necessary.	*
27. Where both FES and orthotic management are available and appropriate, conference concluded that the final choice between the treatment modalities should be made by the patient based on the appearance and ease of use of the respective treatments. <i>N.B. When considering FES, conference was advised that FES referred to functional electrical stimulation and NMES to neuro muscular electrical stimulation and both terms have been used in the literature on stroke rehabilitation.</i>	*
28. The long-term, or "carry over" effects of both FES and lower limb orthotics use have not been proven .	*
29. There is good evidence that BTX-A is effective in reducing lower limb spasticity.	A
30. The evidence of the efficacy of drugs administered orally is stronger (B) than for drugs administered by other means such as intrathecally or chemical neurolysis with phenol or alcohol (C).	B, C
31. Where increased muscle tone interferes with orthotic treatment with regard to fit or function, pharmacological management is considered appropriate. Conference agreed that an improvement of the awareness of this treatment option is recommended.	*

The undernoted recommendations (32-42) resulted from the Syndicate C and General Discussions of Review Papers R7 (Surgery, lower limb) and R8 (Orthotic management of hip and knee).

32. As with AFOs, where standing balance, instability and weight transference are poor, it may be appropriate to consider the early use of a KAFO.	*
33. In the presence of moderate to severe genu recurvatum or when an AFO is unsuccessful in controlling these conditions, then a KAFO should be considered.	*
34. Conference agreed strongly that genu recurvatum should not be ignored. It stressed the importance of identifying the cause, and that prevention, wherever possible, is important. Where there is an underlying problem of increased tone in knee extensor muscles, this should be addressed by other therapeutic means. <i>N.B. Conference was made aware of the development of "new" designs of orthotic knee joints which may offer improved function to patients requiring a KAFO.</i>	*
The following two recommendations apply to all lower limb orthoses (AFO and KAFO).	
35. Alignment of the orthosis at terminal stance/pre-swing is critical and will influence step length, gait symmetry, speed and energy consumption.	C
36. A contracture at any joint of the lower limb may limit the effectiveness of an orthosis.	*

Grade of Recommendation

- 37. There is extrapolated evidence from the literature on the orthotic management of cerebral palsy that a lower limb orthosis can have a positive effect on the range of motion of the hip joint. This is **supported** by the clinical experience of conference. *
- 38. There is a **place** for orthopaedic surgery in the management of stroke patients, however this should not normally be considered in the early phase of recovery. *
- 39. The age of the patient is **not a contraindication** for surgery. *
- 40. Orthopaedic surgery **can be considered** for fixed deformities, correctable deformities (sometimes referred to as 'dynamic) or contractures and a combination of both however *
- 41. Surgery **should only** be a consideration for non-fixed or correctable deformities which are not responsive to other interventions/treatments. *
N.B. The term "dynamic" can be interpreted in different ways. "Volitional" may be a more appropriate /accurate adjective.
- 42. Conference **recommends** that the type of surgery and its functional effects should be informed by clinical gait analysis, both observational and instrumental, when available. Dynamic poly-electromyography is **strongly recommended** prior to surgery when the goal is to improve active function of the limb. Dynamic EMG is not required when the goal is to improve passive range of motion. *

The undernoted recommendations (42-56) resulted from the Syndicate D and General Discussions of Review Papers R9 (Physiotherapy management of upper limb), R10 (Occupational therapy for upper limb), R11 (Pharmacology and upper limb), R12 (FES and upper limb), R13 (Surgery and upper limb) and R14 (Orthotic management of upper limb).

N.B. It was acknowledged that both physio and, more often, occupational therapists have traditionally been responsible for the supply of upper limb and hand orthoses in many clinical settings. This responsibility is shared with orthotists experienced in upper limb management, however appropriately skilled orthotists are often in short supply. This, coupled with the overlap in professional roles which is frequently encouraged in effective stroke rehabilitation teams, has led to some confusion and, at times, heated debate, as to which profession should provide an upper limb orthotic service. As a consequence of this multi-professional management of U.L. problems, there is more literature on the subject of 'orthoses and the U.L.' published by physio and occupational therapy practitioners. Conference agreed, however, that the research findings remain, in general, inconclusive and P.T. and O.T. orthotic interventions for the arm and hand remain controversial.

Conference made the following recommendations:

- 43. The **General Recommendations** (points 1-15), conclusions and recommendations) **apply** equally to upper limb and lower limb orthotic management. *
- 44. Conference **recommended** that in an ideal situation, where both trained orthotic and therapy staff are included in the stroke team, the complexity of the device will determine who should provide the orthosis i.e. more complex orthoses should be provided by orthotists. *
Temporary upper limb orthoses and off-the-shelf devices with relatively simple "fitting" requirements **may** be provided by appropriately trained professional staff other than orthotists e.g. occupational therapists, physiotherapists and nurses with specific skills in this area.
- 45. Team training in the design, use and fitting of upper limb and hand orthoses is **strongly recommended**. *
- 46. Well identified, measurable goals should be **agreed** by the clinic team in conjunction with the patient. *
- 47. Although the relationship between shoulder pain and subluxation is not absolute, there is **weak evidence** and a clinical rational behind the institution of shoulder supports as an adjunct to physiotherapy. C*
- 48. The design of any shoulder orthosis, in common with all orthotic devices, **should be:** *
easy to don/doff
cleanable
of a design which allows the patient to be cleaned

	Grade of Recommendation
49. Orthotic treatment of the upper limb and hand should be considered during the early rehabilitation phase, with the emphasis on prevention of contracture and deformity and on enabling function	*
50. The evidence in support of the use of lycra cuffs, reinforced elastic bandages, airsplints and resting splints is weak .	C
51. There is good evidence of the positive effect of repetitive function and strength training for the hand and upper limb.	A
52. There is conflicting evidence about the efficacy of constraint induced therapy and robot-aided training for dexterity of the upper paretic limb.	*
53. There is no compelling evidence that an upper limb neuroprosthesis based upon present technology is effective in improving hand function of stroke patients.	C
54. There is good evidence that pharmacological treatment can reduce muscle tone. Treatment is likely to be most effective when it is combined with other therapies including orthotics and surgery.	B
55. There is strong evidence that the use of botulinum toxin reduces spasticity in the upper limb and hand.	A
56. Studies of surgery for the upper limb and shoulder have been conducted for many years with some positive results. Numbers of patients tend to be small, however, and the research methodology weak. Conference recommends that more evidence is needed to scientifically establish the effectiveness of using orthopaedic surgery to treat upper extremity dysfunction or deformity following stroke.	*

The undernoted recommendations (57-62) resulted from the Syndicate E and General Discussions of Review Papers R15 (Service delivery issues), R16 (When to prescribe orthoses), R17 (Scores, scales and outcome measures) and R18 (Current research in orthotics).

57. Conference agreed that a range of measures will be needed from which researchers and clinicians can select the most appropriate measure(s). A list of validated measures of impairment, activity and participation or function which may be of use in studies of orthotic intervention after stroke is included in this report (Appendix 3).	*
58. The majority of studies included in the review of outcome measures have chosen measures of impairment matched to the aims of the orthotic intervention tested, however many studies have not monitored these effects at the level of walking function. Conference recommends that studies of orthotic intervention should include, wherever feasible, measures of function which are of relevance to the patient, and that issues broadly defined as "quality of life" and which may be influenced by orthotic intervention should also be measured.	*
59. Any chosen outcome tool should match the aim of the orthotic intervention and demonstrate the key measurement attributes of validity, reliability and sensitivity. For evaluative instruments, sensitivity to clinically important change is an additional requirement for validity.	*
60. There was agreement that the great majority of published studies on the subject are low in the hierarchy of levels of evidence. Conference has made recommendations earlier in this report which may go some way to improve the quality of research evidence.	*
61. Conference further recommends the initiation of multi-centre, even multi-national trials where large groups of patients are entered into rigorously conducted, methodologically sound research projects which are sufficiently large to answer the research questions with the least chance of statistical error. To be fully effective, this can only take place after the recommendations on standardising terminology and definitions have been implemented.	*
62. Conference strongly supports the concept of multi-professional research into the orthotic management of stroke patients.	*

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APPENDIX A

GLOSSARY OF RESEARCH TERMS

Christopher Morris MSC, SR Orth

RESEARCH	Some systematic and unbiased method of answering questions.
EFFICACY	Whether an intervention demonstrates a treatment effect in controlled experimental conditions.
EFFECTIVENESS	Whether an intervention demonstrates a treatment effect in routine clinical practice.
EFFICIENCY	Economic and expedient delivery of health services.
RESEARCH METHODOLOGY	Selecting an appropriate research design to answer the specified question.
OBSERVATIONAL RESEARCH	Descriptive information is collected but events are not influenced by the researchers.
EXPERIMENTAL RESEARCH	The researchers deliberately influence events and monitor what happens as a result.
CONTROL	In order to test if a new intervention has a treatment effect we need a comparison patient or parallel group that is treated in some other way, standard treatment or placebo.
BLINDING	The extent to which clinicians, patients and those evaluating outcomes can be prevented from know which treatment has been allocated in a clinical trial, this is difficult in orthotics.
BIASES	Fair tests of treatments require the avoidance of bias at all stages in the research process, including: how patients are selected, that comparison treatments are appropriate, allocation of treatment is concealed from clinicians, observer or measurement error is minimised, that all results are reported. (www.jameslindlibrary.org)
RANDOMISED CONTROLLED TRIAL	Subjects are randomly assigned to groups that vary only by their exposure to the intervention. Statistical analysis is between groups.
META-ANALYSIS	Statistical aggregation of the results of several separate but similar studies.
CONTROLLED CLINICAL TRIAL	An experiment where an intervention is compared with another or no treatment but there is no attempt to randomly allocate subjects to different groups.
COHORT STUDY	A group is opportunistically identified by their exposure to a medical intervention or noxious agent, followed and their outcome compared with another group not exposed to the agent or treatment; for example identifying subjects 'using' and 'not using' an AFO and following them up to see whether there is a difference in the proportion in each group that develops ankle equinus. Cohort studies are therefore prospective.
CASE-CONTROL STUDY	A group is identified because they have an outcome (the cases) and their exposure to a medical intervention or suspected agent is compared with a group that do not have the outcome (the controls). For example, identifying subjects who have a fixed equinus deformity and those who do not, and investigating whether there is a difference in the proportion in each group that used an AFO. Case-control studies are retrospective. The difference between cohort and case-control studies may be confusing, the issue depends upon whether subjects are identified by their exposure to a causal agent (cohort) or whether they are identified by having sustained some outcome (case-control). This affects the procedures for statistical analysis.

<p>WITHIN SUBJECT COMPARISON STUDY</p>	<p>Also called a 'before and after' design, the subject acts as their own control, for instance walking with and without an orthosis at one point in time. A more rigorous approach follows the subject for longer making several assessments; this is a time-series study.</p>
<p>CROSSOVER STUDY</p>	<p>A variation of the within-subject comparison design, subjects receive all the treatments being compared, usually in a random order. A period of no treatment usually occurs between comparison interventions to allow the effects of the first treatment to washout. For example providing subjects with either a rigid or hinged AFO for a month and then after two weeks of no treatment providing the other type of AFO, and comparing subjects functional ability between the two types of AFO. Statistical analysis is within groups.</p>
<p>CROSS-SECTIONAL STUDY</p>	<p>In a cross sectional study all the information is collected about subjects at one point in time. These are usually descriptive studies, called surveys, but can also be used to explore associations.</p>
<p>SAMPLE SIZE</p>	<p>The number of subjects required in an experiment testing a hypothesis that is likely to detect a worthwhile and statistically significant effect when it exists, and conversely, not find an effect when it does not. Without calculating a sample size two types of error are risked:</p> <p>Type I or α error - Believing there are benefits from orthoses when it fact there are not.</p> <p>Type II or β error - Rejecting using orthoses which may actually confer benefit.</p>
<p>CONFIDENCE INTERVAL</p>	<p>When it has not been possible to calculate a sample size results can be presented together with a range of values within which the true value is expected to be, this is the confidence interval (CI) and is usually set at 95%. This means the true value can be expected to be within the specified range 95% of the time, however it is also possible to calculate a 99% CI. The wider the range represented by the confidence interval the less precise the result, and conversely the narrower the range the more precise the result.</p>
<p>HEALTH STATUS MEASUREMENT</p>	<p>Patient and family self reports of their abilities or quality of life are now commonly used along side more conventional indicators of health in clinical trials and routine practice. Discriminative measures are used to tell people apart, for example by the severity of their movement ability, by contrast evaluative measures are responsive to change in individual's abilities.</p>
<p>RELIABILITY</p>	<p>The reliability of an assessment or outcome measure, for example a clinical test or quality of life questionnaire, reflects the amount of systematic or random error inherent in the measure. Forms of reliability include the reproducibility of observations made by different people (inter-observer), or observations made by the same person (intra-observer), or by an instrument on different but unchanging occasions (test-retest).</p>
<p>VALIDITY</p>	<p>The validity of a measure is the extent to which it measures what it claims to measure. Validity is often tested against a known criterion, hypothetical construct or examined for the appropriateness of its content. Sensitivity to change, or responsiveness, is fundamental to the validity of an evaluative measure, that it is capable of detecting clinically important change.</p>

APPENDIX B

GUIDELINES FOR STROKE REHABILITATION RESEARCH

Robert C. Wagenaar, PhD

INTRODUCTION

A rather large number of intervention studies have been published in the domain of stroke treatment (Wagenaar & Meijer, 1991a&b). At first sight, reported results appear to be inconclusive or even inconsistent. The heterogeneity of the population involved has been indicted as a major factor jeopardizing research in this area (e.g., Basmajian & Gowland, 1987; Sterman et al., 1987; Wade, 1987). Indeed, both 'natural' and 'intervention' outcomes are influenced by patient characteristics, such as the side, localization and extent of the lesion, the presence of neuropsychological deficits, degree of motivation, stage of recovery, gender, etc (Kwakkel et al., 1996). In order to cope with intersubject variability, Basmajian and Gowland (1987) contended that one needs to define the natural history of recovery, and classify its various patterns over time, before designing intervention studies. The establishment of such a classification system could be the key to better research and better care of patients.

Recent research syntheses, however, provide adequate evidence that rehabilitation can have a positive influence on recovery patterns (Matyas & Ottenbacher, 1993; Schleenbaker & Mainous, 1993; Glanz et al., 1995 & 1996; Langhorne et al., 1996; Kwakkel et al., 1997). The findings of two randomized controlled trials indicate beneficial effects of higher intensity of stroke rehabilitation (Kwakkel et al., 1999) and forced-use of upper extremity function (van der Lee et al., 1999). The evidence suggests that randomized controlled trials with sufficient contrast between experimental and control groups, involving large study populations (e.g., N=30 experimental condition), and, thus, sufficient power, allow the detection of differences in treatment efficacy (see Kwakkel et al., 1996). The remaining question appears to be whether the reported effects are clinically relevant. For example, Van der Lee et al. (1999) reported small but lasting effects of forced use on the dexterity of the affected arm and the amount of use of the affected arm during activities of daily living. The effects were only clinically relevant in the subgroups of patients with sensory disorders and hemineglect.

Those involved in 'neurological rehabilitation' (Wade, 1987), will be inclined to agree with the 'Call for Action' by Basmajian and Gowland (1987) surveying the natural history of stroke. However, it is our contention that controlled single case experimental design or interrupted time series (ITS) experiment may contribute to efficiently trace natural histories. In addition, by using the patients as their own (experimental) control and repeated measurements over time within one subject knowledge will be obtained concerning the efficacy of stroke treatment. According to Basmajian and Gowland (1987), however, 'we are confronted by the same barrier - ignorance of the natural history of the individual cases'. Single case methodology has been used increasingly in studying the effects of stroke rehabilitation (Wagenaar, 1990; Backman et al., 1997). In general, authors claim that the advantages of ITS methodology may outweigh its disadvantages.

Critical issues in the methodology of intervention studies appear to be 1. methods of data analysis ('statistical validity'), 2. the specific design used ('internal validity'), and 3. the generalizability of results ('external validity'). The aim of this study is to present a framework for the analysis of intervention studies in the field of stroke rehabilitation. In order to understand experiments in complex field settings, Campbell and Stanley (1963), and later Cook and Campbell (1979), introduced a detailed framework for analysis.

Concerning changes after treatment, or the lack thereof, Cook & Campbell (1979; see also Campbell & Stanley, 1963) posed four major questions, i.e.: 1. Could this be a chance observation ('statistical validity')?, 2. What would have happened without the treatment ('internal validity')?, 3. Is this empirically generalizable ('external validity')?, and 4. In how far is this theoretically relevant ('construct validity')? Campbell and Stanley (1963) listed factors jeopardizing the different types of validity and classified research designs along the lines of experimental control: no-control (i.e., 'pre'), randomization ('true'), or other types of control ('quasi experimentation'). Both their style of reasoning and theoretical framework were developed in the context of educational research and have become paradigmatic for the evaluation of intervention studies. At least for the present analysis, being directed to practical methods of rehabilitation, theoretical relevance has been left out (question 4). 'Confounding' (or 'Hawthorne effect' or 'placebo effect'), initially listed under external validity (Campbell & Stanley, 1963), later under construct validity (Cook & Campbell, 1979), will be regarded as part of internal validity (question 2 becomes: What would have happened without the specific parts of the treatment?). Advantages and disadvantages of specific designs will be analyzed in terms of statistical, internal and external validity, using actual clinical trials in stroke rehabilitation throughout to illustrate the argument. Logically, internal validity presupposes statistical validity. Since, however, internal validity (question 2) is strongly related to the overall structure of the design, it will be analyzed before statistical validity (question 1) and external validity (question 3).

INTERNAL VALIDITY OF INTERVENTION STUDIES

Internal validity refers to the extent the outcome of an intervention study can be related to the treatment. In other words: What would have happened without the treatment.? Based on the work of Campbell and his colleagues (Campbell & Stanley, 1963; Cook & Campbell, 1979), factors jeopardizing internal validity of intervention studies will be classified into the following five major source categories: 1) initial characteristics of the patient (selection bias); 2) circumstances during the study (contamination); 3) the effect of repeated measurements (reactive effect); 4) the effect of treatments in preceding phases on ensuing phases (carry-over); and 5) non-specific parts of the

treatment (confounding). Observed changes over time may be caused by the specific parts of the treatment, but the other systematic sources of variances do offer alternative explanations. Internal validity is, therefore, enhanced by controlling for the alternatives. To the extent that it is possible to rule them out, it may be concluded that the specific parts of the treatments were, indeed, causally related to the observed changes, so that it may be said that the design is internally valid. To enhance internal validity, a control group receiving no (specific parts of the) treatment (between-group experiment) or a baseline phase or period during which measurements are repeatedly taken, while the patient receives no (specific parts of the) treatment (ITS experiment), may be used. Different treatment conditions are then compared with the control condition and/or each other (in the case of more than one treatment condition). Since the success of experimental designs relates to the extent other systematic sources of variance are controlled for, designs will be categorized as pre-experimentation, quasi-experimentation and true-experimentation and discussed accordingly.

PRE-EXPERIMENTATION

Pre-test/post-test group experiment

No methodology is applied in pre-test/post-test group studies, where the patient is assessed before the start of the treatment and immediately after. The pre-test is supposed to reflect the state of the patient without the treatment. By comparing the pre- and post-test results statements are made about the treatment effect. An example of a pre-test/post-test group study in the field of stroke rehabilitation has been presented by Kaplan (1962).

In a study starting more than nine months post stroke, Kaplan (1962) has evaluated the efficacy of a dorsal hand splint. Comparing the pre- and post-tests Kaplan observed that reflex activity, range of motion (ROM) and muscle strength were improved, whereas no relevant changes were signaled in terms of functional tasks.

Obviously, the observed changes in reflex activity, ROM and muscle strength could be due to alternative factors, such as maturational processes (selection bias), coincidental events in the environment (contamination), the patients' gaining skill in performing the tests (reactive effect), or a positive reaction to the sheer fact of being treated (confounding). Due to its lack of internal validity the pre-test/post-test design is regarded as a 'pre experiment'.

ITS experiment

Minimal methodology is applied in the AB design, where the patient is initially assessed during a non-treatment condition ('baseline' or A-phase), subsequently during the implementation of a specific treatment (B-phase). The baseline is supposed to indicate the state of the patient without the treatment. Authors generally claim (e.g., Barlow et al., 1977; Ottenbacher, 1986) that the baseline should be 'stable' - often operationalized as 'horizontal'. Major differences in level or trend of the A- and B- phases, are then assumed to indicate a treatment effect. An example of an AB design in the field of stroke rehabilitation has been presented by Goodkin (1966).

A patient with a right hemiparesis tried to relearn how to operate a keypunch machine (for punching holes on IBM cards) with her non-dominant hand. The efficacy of verbal reinforcement on duration and number of responses was evaluated (see Fig. 1). Goodkin observed that the patient had made little progress for several months before the trial. Two baseline assessments were supposed to confirm this pattern. During the specific treatment, improvement was observed. It was concluded that verbal reinforcement resulted in considerable progress.

The AB design introduces some major problems regarding internal validity. Despite his results, Goodkin stated that a more systematic behavioral approach would be necessary for evaluating the efficacy of his reinforcement technique. Again, the observed response pattern could be due to alternative factors, such as selection bias, contamination, reactive effects, or confounding. Due to its lack of internal validity (see Connolly et al., 1983), it is proposed to regard the AB design as a 'pre experiment'.

In order to gain internal validity with respect to selection bias and contamination, a control group or some form of phase replication (e.g., an ABAB or a multiple baseline (or AB) design replicated across subjects) should be introduced. Upon such replication, reactive effect and carry-over can be excluded only if performance decreases during some later phase. Finally, control for confounding implies that one intervention condition should be added to the control group or A-phase, that contains all non-specific aspects of the treatment ('placebo').

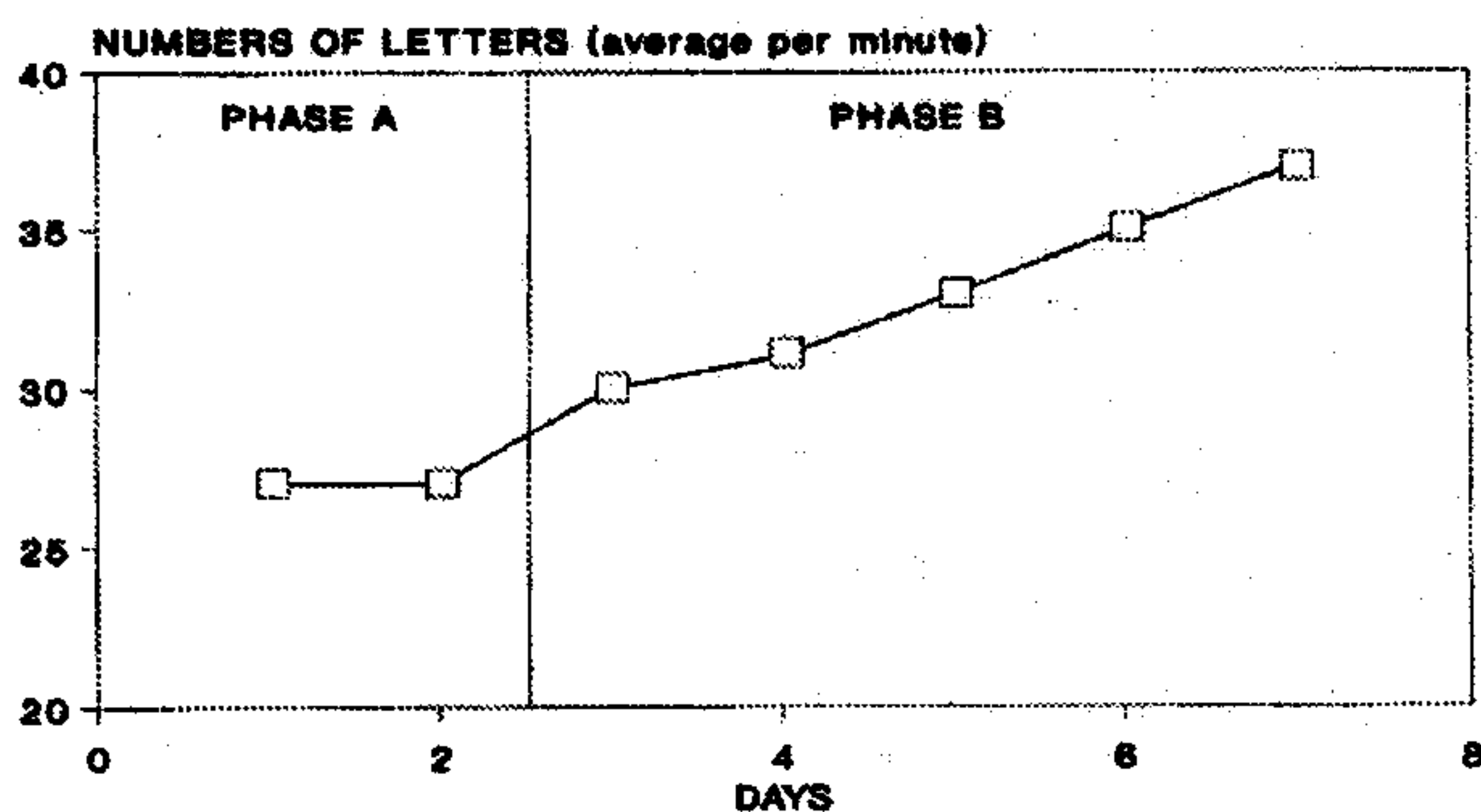


Figure 1. Change in average response time (left) and number of words per minute (right) on a keypunching machine after verbal reinforcement.

QUASI-EXPERIMENTATION

Between-group experiment

Including a control (or reference) group in the pre-test/post-test design receiving no therapy or therapy without the specific parts of the experimental treatment, may allow for causal inferences linking the differences in gains in recovery observed between the experimental group and the control group to the treatment. The rationale for introducing a control group in general is, that maturational processes (selection bias), coincidental events in the environment (contamination), and the patients' gaining skill in performing the tests (reactive effect) are expected to occur in both groups. Taking a reference group receiving treatment without the specific elements of the experimental condition may allow for causal inferences linking the larger improvements observed in the experimental group compared to the control group to the specific parts of the experimental treatment. An example of a between-group study without randomization on the effects of specialized care, is presented by Strand et al. (1985).

Strand et al. (1985) found in a study on 293 patients, that a significantly higher percentage of patients became ADL independent when treated on a stroke rehabilitation ward in comparison to a medical ward. Significantly fewer patients on the stroke rehabilitation ward were hospitalized or sent to a nursing home. In addition, they found sustained effects for dressing and personal hygiene after one year. Strand et al. (1985) speculated that this result might be a consequence of active family participation in the stroke rehabilitation ward program.

By including a reference group, Strand and his colleagues reduced selection bias, contamination and reactive effects as possible explanations for the larger improvements observed in the experimental group compared to the reference group. However, the internal validity of the study could have been improved by 1) randomly allocating of patients across experimental and control groups, and/or 2) matching the patients of both groups on the basis of relevant patient characteristics. These procedures reduce the likelihood of finding statistical differences between the two groups in patient characteristics at baseline, and, hence, the possibility that the differences in efficacy are caused by selection bias. Hence, the study of Strand and his colleagues is to be designated as a quasi-experiment. In a between-group design (without a cross-over design in which intervention phases are repeated) carry-over effects of treatment conditions are excluded. By comparing the effects of a stroke rehabilitation ward to those of a medical ward, Strand et al. also controlled for confounding. However, one should be careful in interpreting the results of the study as 21 out of the 110 patients in the experimental group participated also in a therapeutic trial on the effects of hemodilution in acute ischaemic stroke.

ITS experiment

Extending the AB design with at least one more phase, during which the therapy is withdrawn (alternating AB or reversal design; e.g., Hersen & Barlow, 1982), may allow for causal inferences linking the treatment and the state of

the patient (ABA, ABAB, or also BAB, BABA, etc.). The underlying logic for introducing this second (third, etc.) 'switch' in therapeutic conditions, is that one concurrence between changes in the patient and in therapeutic conditions may be incidental, while two or more are likely to reveal a causal relation.

Ostendorf and Wolf (1981) used an ABA design to examine the effect of the forced use of the affected arm of a patient with a 'chronic' right hemiplegia. During treatment, the non-affected arm was kept under restraint. The authors assessed the quantity, quality and efficiency of functional behaviors, including 17 motor behaviors needed in activities of daily living (ADL). On visual inspection of the graphically displayed data derived from the patient's self-reports (see Fig. 2), the total quantity of functional behaviors per day appeared to increase during the treatment phase, and, subsequently, to decrease somewhat during the second baseline.

With respect to selection bias and contamination, alternating AB designs do not control for such oscillatory trends, the rhythm of which happens to coincide with the switching of the phases; biorhythms or seasonal trends in the patients or their circumstances. Ostendorf and Wolf used three phases of one week each (see Fig. 2). Since a week is a rather 'natural' unit in our culture, phases of exactly one week may jeopardize internal validity. Hence, randomizing the phase length of the different phases increases experimental control. Alternating AB designs can be categorized as 'true experiments' whenever phase length has been randomized (or, in the case of a replication on different subjects, a randomization of phase order), but otherwise as 'quasi experiments'. Ostendorf and Wolf's study, thus, is to be designated as a quasi experiment.

Control for reactive effects is obtained post hoc, as soon as the value of the assessment variable decreases during the second A phase; as was the case in the study by Ostendorf and Wolf (see Fig. 2). Accordingly, in a BAB design, reactive effects can be excluded if performance decreases during the first and only A phase. A further problem of single alternating AB designs is that they can only relied upon if the effect of the treatment is non-permanent. In Figure 2 one gains the impression that some carry-over effect remained present after withdrawing the therapy. Replicating the design with randomization of phase order (ABA or BAB), may help to trace such carry-over effects.

Ostendorf and Wolf themselves stated that their results were not conclusive as to the efficacy of 'forced use' in recovery from hemiplegia. Perhaps, they argued, the motivation of the patient - influenced by the experimental set-up - had been an important factor in changing the quantity, rather than the quality, of functional behaviors. This concern reveals that an alternating AB design with a non-treatment baseline, does not eliminate confounding. Including non-specific parts of the treatment in the baseline, or including a phase with another treatment similar qua placebo, appears to be the only solution to this problem.

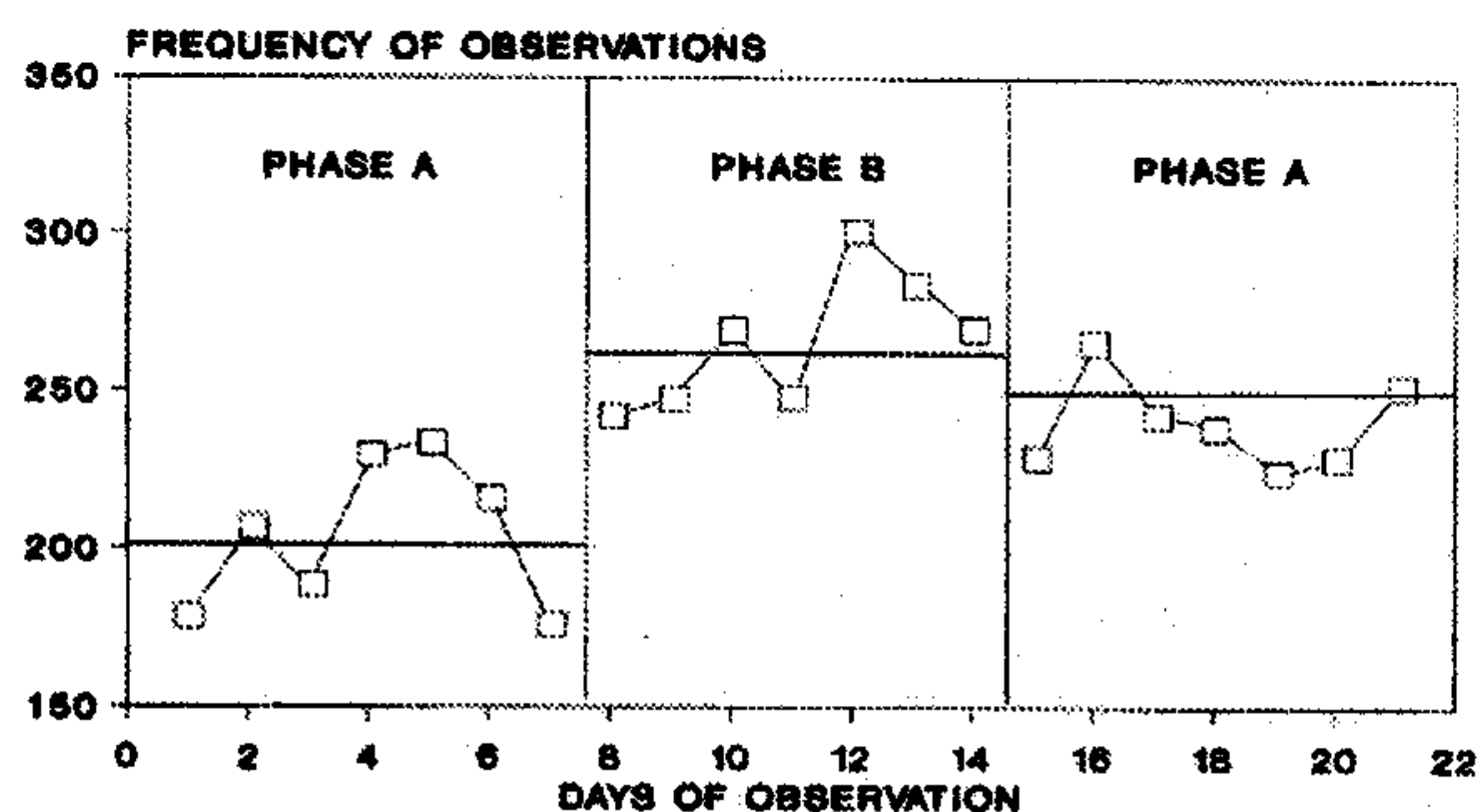


Figure 2. Change in number functional behaviours per day during forced use. (Adapted with permission from Ostendorf & Wolf, 1981, p. 1026.)

TRUE-EXPERIMENTATION

Between-group experiment

A randomized controlled trials (RCT) with a between-group design is generally regarded as providing the best evidence. Random allocation of patients across experimental and control groups reduces the likelihood that patients with different characteristics are unevenly distributed between groups, and, hence, controls for selection bias, allowing for causal inferences linking the treatment and the state of the patient. An example of a randomized controlled (between-group) study on the effects of intensity of stroke rehabilitation, is presented by Kwakkel et al. (1999).

Kwakkel et al. (1999) investigated the effects of different intensities of arm and leg rehabilitation training on the functional recovery of ADL, walking ability, and dexterity of the paretic arm in a single blind randomized controlled trial. Within 14 days after stroke onset, 101 severely disabled patients with a primary middle-cerebral-artery stroke were randomly assigned to: a rehabilitation program with emphasis on arm training; a rehabilitation program with emphasis on leg training; a control program in which the arm and leg were immobilized with an inflatable pressure splint. The treatment protocols included guidelines for treatment based on best evidence, for the first twenty weeks post stroke. The patients were assessed weekly up to week 20 with follow-up assessments at 26 and 50 weeks post stroke. It was found that greater intensity of leg rehabilitation significantly improves ADL, walking ability (compared to arm rehabilitation and control program), and dexterity (compared to control program), whereas the arm rehabilitation group differed significantly from the control group only in dexterity. The improvements in ADL and walking ability were already significant after 6 weeks of leg rehabilitation, whereas the improvement in dexterity was significant after 12 weeks of arm rehabilitation. The improvement in walking ability was also reflected in a significant improvement in comfortable and maximal walking velocity. No significant differences between the three conditions were found during follow-up assessments 50 weeks post stroke.

A RCT with a between-group design controls for selection bias, when patient characteristics are evenly distributed across experimental and control groups, which was the case in the study of Kwakkel and his colleagues. The study took

place at different sites (acute care hospitals, rehabilitation hospitals, nursing homes and out-patient facilities), and therefore (block) randomization was carried out in the eight main hospitals in which patients were admitted. This reduced the impact of different (environmental) settings (contamination). In a between-group design, carry-over effects of treatment conditions are excluded. By including the non-specific parts of the treatment (e.g., number of treatment sessions, duration of treatment protocol, etc.) in the reference condition Kwakkel et al. successfully controlled for confounding.

The study by Kwakkel and his colleagues combined a RCT with a repeated measures design and, hence, is a true experiment. The size of the patient population and the contrast between treatment conditions were sufficient to allow differences in efficacy to emerge. The power of the study was further increased, by including a repeated measures design. However, it is open to further investigation, which patients benefit from higher intensities of rehabilitation.

ITS-experiment

Using more than one AB design, with different or staggered length of A phases (multiple baseline design), may remove several disadvantages from the alternating AB design (cf., Kazdin, 1982; Ottenbacher, 1986). The 'multiple baseline design across subjects' is executed over different patients treated similarly. In the 'multiple baseline design across behaviors', executed on a single patient, the treatment is directed at different targets; each targeting being initiated at a randomly different moment. Finally, the 'multiple baseline design across settings' specifically tries to establish if the treatment is successful in different circumstances.

Gianutsos et al. (1986) combined a multiple baseline design across subjects with one across behaviours, evaluating the efficacy of visually displayed EMG feedback in the treatment of chronic hemiplegic upper limb disorders. Five patients were allocated to baseline conditions ('Do your best') of randomly different length, after which visual feedback was given for three different, randomly ordered, target behaviours, i.e., shoulder flexion, elbow extension (or flexion), and finger extension. EMG activity of both agonist and antagonist muscles was registered. In order to avoid confounding, patients were connected to the machine throughout all phases, and no information concerning EMG activity was given during assessment. Patients showed consistent changes in elbow function only; the relevant data of one patient are demonstrated in Figure 3. According to Gianutsos et al., increased motivation after a period without therapy, or the presence of sophisticated equipment, could not fully account for the observed changes: they concluded that EMG feedback was effective, that is, at least for elbow function.

The multiple baseline design with staggered lengths of A-phases controls for selection bias and contamination, whether ephemeral or sinusoidal. As long as baseline lengths are indeed different and improvement is observed upon initiating each B phase, reactive effects may be excluded. Carry-over effects of the specific treatment are

excluded, but 'transfer' over different target behaviours may be controlled for if and only if different patients are used (see Gianutsos et al.). Control for confounding implies including the non-specific parts of the treatment in the baseline; for example, 'being connected to the machine throughout all phases', as in the study Gianutsos et al. The multiple baseline design with randomized lengths of A-phases can be regarded as a 'true experiment' and the design without randomization as a 'quasi experiment' (see Table 1). The study by Gianutsos et al., then, was a true experiment. Nevertheless, Gianutsos et al. may have missed a confounding factor. In a controlled group study with hemiplegic patients, Hurd et al. (1980) found no significant differences between actual (audiovisual) and simulated feedback (determined by the therapist's estimate of the patient's efforts). Hence, it remains to be seen if the placebo condition of Gianutsos et al. (i.e., no feedback) was, in itself, sufficient.

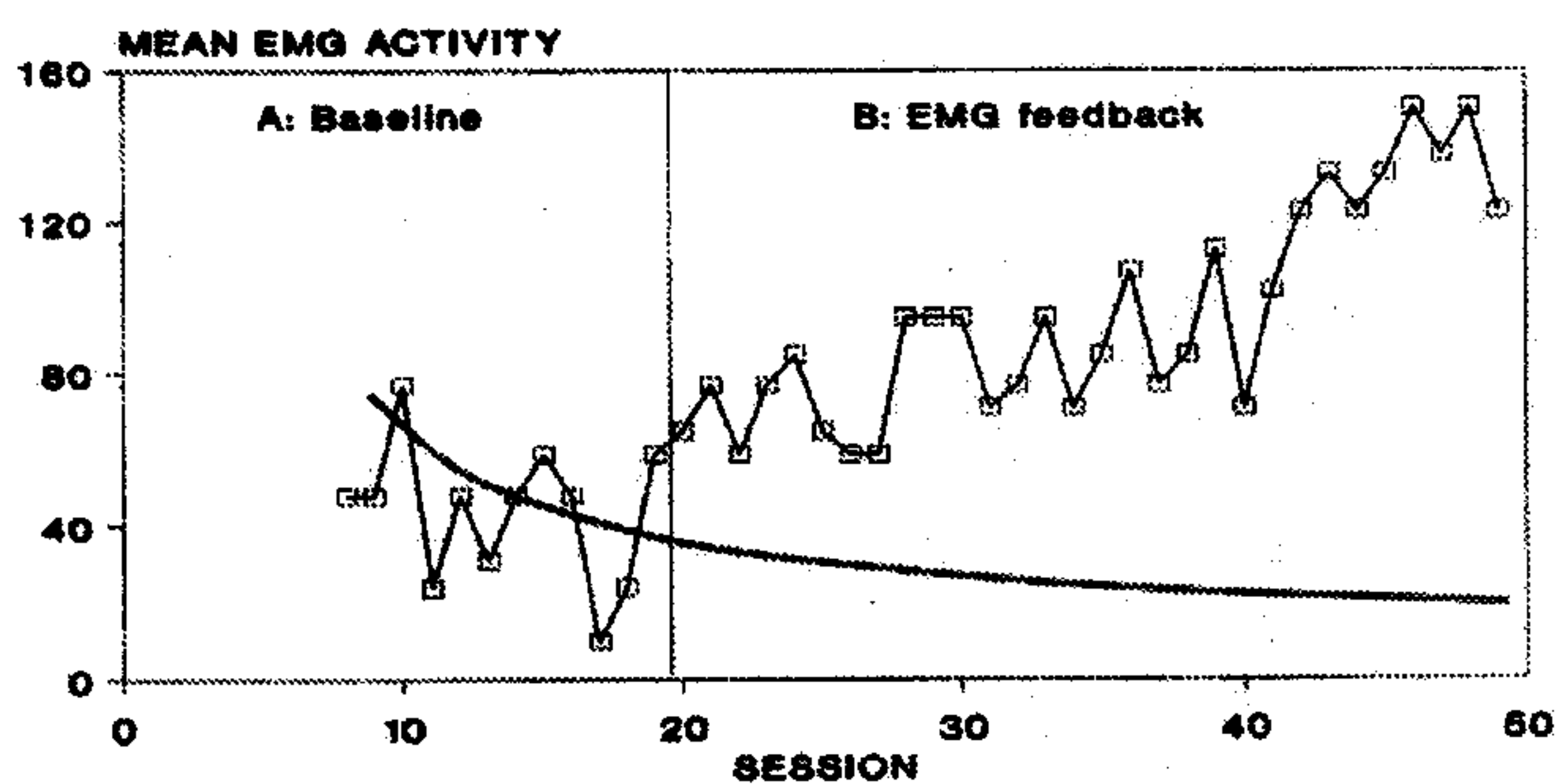


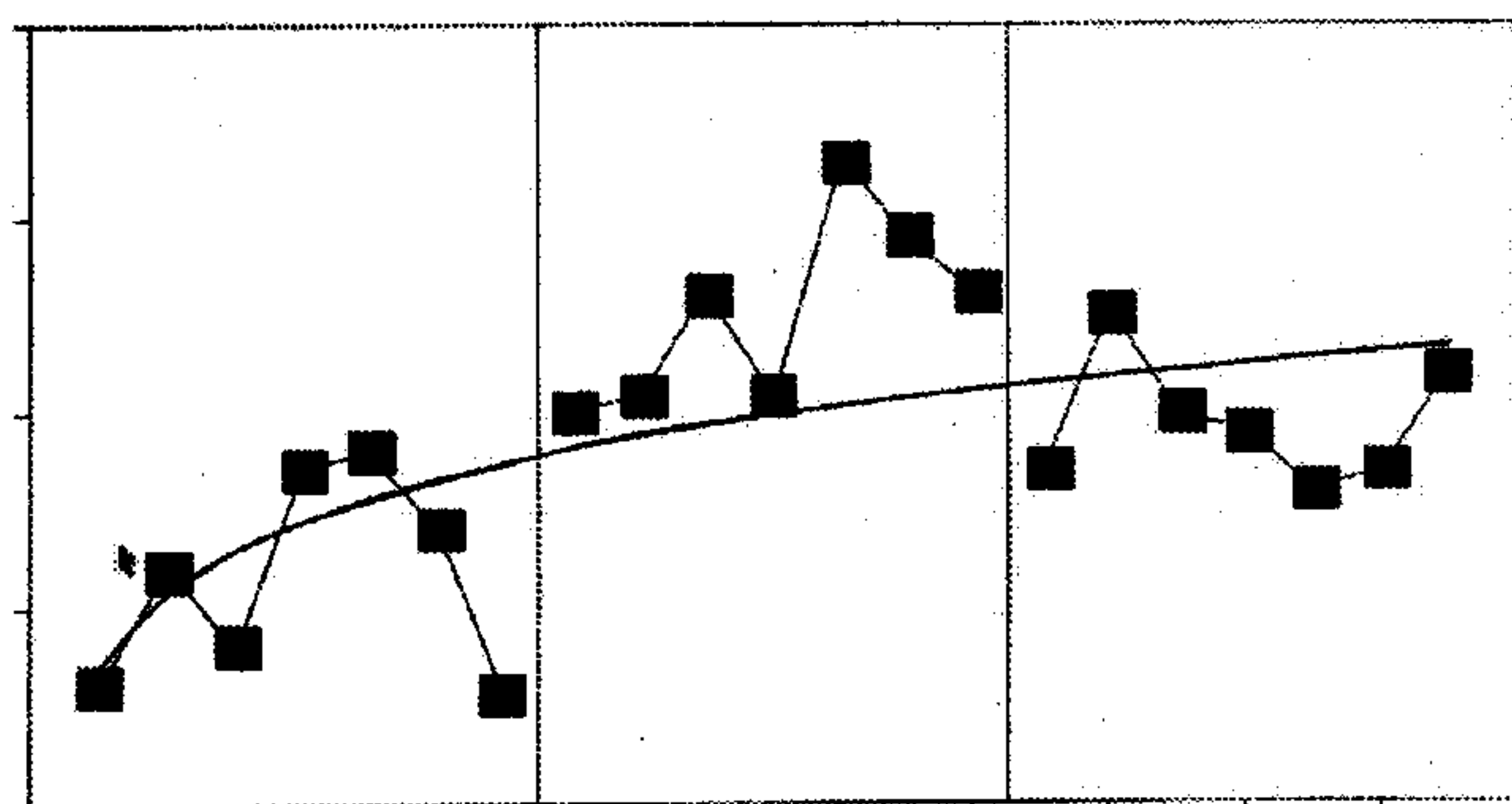
Figure 3. Change for one patient in elbow function (biceps minus triceps activity) during visual EMG feedback.

STATISTICAL VALIDITY

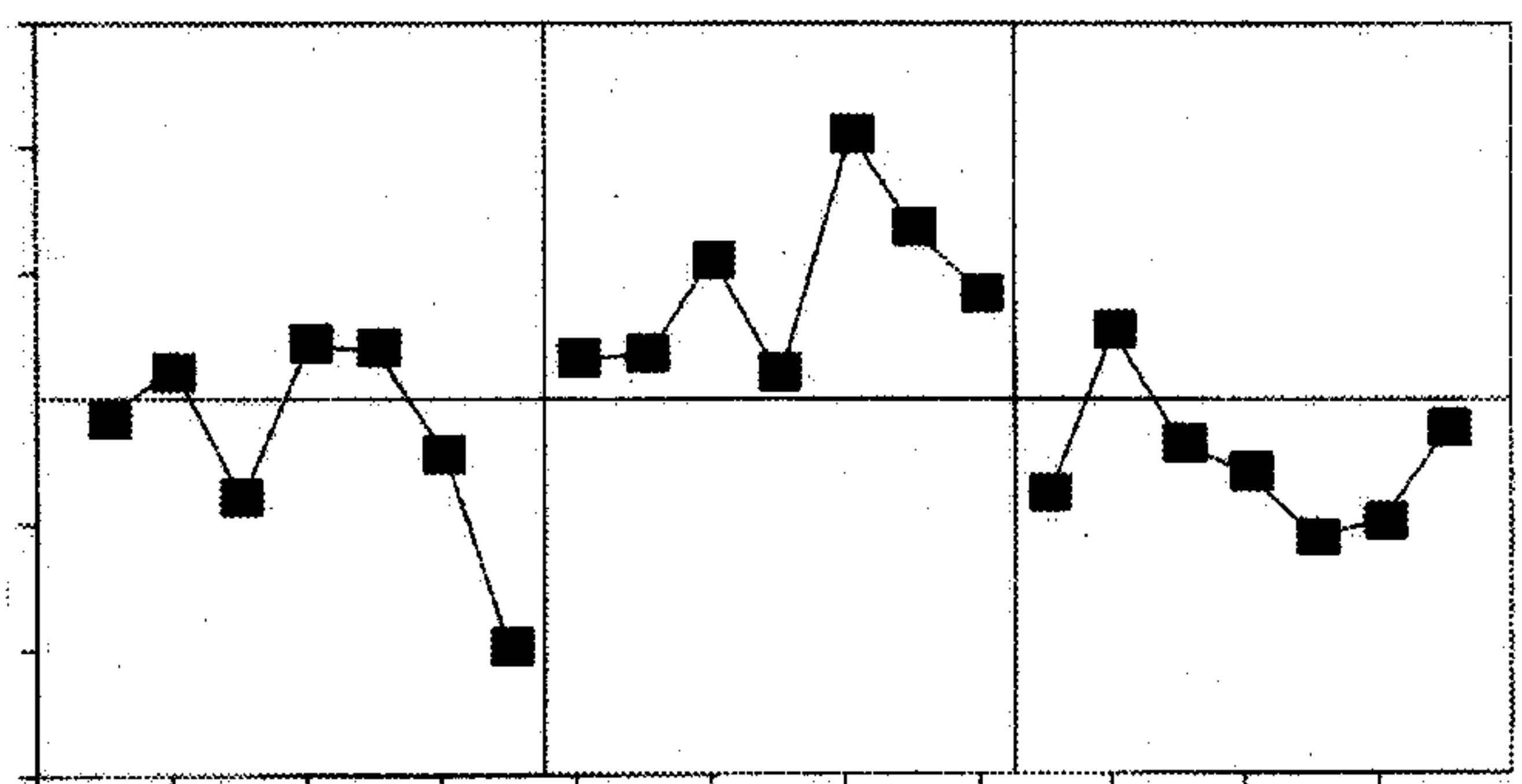
The perennial question is if the changes found between groups or between intervention phases within one subject or a group, are caused by differential treatment effects or by general trends. Both visual inspection and statistical analysis are often applied in the analysis of intervention studies. For example, Kaplan (1962), Goodkin (1966) and Ostendorf and Wolf (1981) relied upon visual inspection of the pre- and post-tests or individual time series, whereas

Strand et al. (1985), Kwakkel et al. (1999) and Gianutsos et al. (1986) based their findings on statistical analysis. Studies that do not include statistical analysis are statistically invalid (see Kaplan, 1962). For example, in Goodkin's case (Goodkin, 1966; see Fig. 1) the number of data points in the baseline is insufficient for statistical comparison between treatment with no-treatment condition, and visual inspection of time series is insufficient. The time series on change in average response time (see Fig. 1a) suggest that the baseline was stable. However, the time series on the number of words key punched per minute (see Fig. 1b) in the baseline indicate that an increment in the number of words punched in the B-phase is to be expected. Therefore, the design is a statistically invalid pre experiment.

Ostendorf and Wolf (1981; see Fig. 2), again, confront one with the 'perennial' problem of ITS- experimentation, i.e., whether changes have to be captured by means of visual inspection only, or through inferential statistics (e.g. Hojem & Ottenbacher, 1988; Kazdin, 1982; Ottenbacher, 1986; Wolery & Harris, 1982). Ostendorf and Wolf relied on visual inspection of the mean values based on the seven data-points in each phase. In their data, it may appear to be 'visually certain' that the treatment phase is 'better' than the first baseline but the difference with the second one is less outspoken. However, visual inspection of the complete time series suggests a general linear trend. Horne et al. (1982) indicate that when less than 35 data points are available within each intervention phase, a single (regression) model should be formulated for all intervention phases. Therefore, the figure in the publication was computer scanned and the data were reconstructed. Upon statistical analysis, a significant linear regression was, indeed, revealed ($p = 0.015$; see Fig. 4a). After removing this trend (see Fig. 4b), the autocorrelation function revealed no serial dependency within the residuals. Further analysis suggested that the treatment phase appeared to be 'better' than both baseline phases (Mann Whitney U-test: $p < 0.002$ and $p < 0.003$ respectively). The fit of a non-linear function to Ostendorf and Wolf's data is more tight ($p = 0.009$; Figure 4c) than of a linear one, but again, the uncorrelated residuals show significant differences (Mann Whitney U-test: $p = 0.01$ and $p = 0.003$ respectively, Figure 4d).



A



B

Figure 4. Our analysis of the data of Ostendorf and Wolf (cf. Fig. 2.) a. Linear regression analysis; b. Residuals after removing linear trend; c. Non-linear regression analysis; d. Residuals after removing non-linear trend.

Hence, the presented statistical analysis does not invalidate Ostendorf and Wolf's conclusions. If one of the baselines had contained the non-specific parts of the treatment and the phase lengths had been randomized, such data would have established a 'treatment effect' beyond reasonable doubt, given the history of the individual patient.

The statistical procedure used, needs to have been described and p-values reported, in order that a judgment can be made as to whether or not the result obtained could be due to chance. When this information is missing or inaccurate, the intervention study is regarded as statistically invalid. Furthermore, from a group study, in which the gains within each group are separately analyzed without statistically comparing the gains of all groups involved, no valid conclusions can be drawn with respect to differential efficacies. The statistical analysis should compare the gains of all groups or intervention phases involved in the study.

In between-group studies it is important to determine whether at baseline (or pre-tests) there are statistically significant differences between groups in patient characteristics. Variables revealing these differences need to be included as co-variables in the statistical analysis (see Van der Lee et al., 1999). If these differences at baseline exist and are not included in the statistical analysis the study is again a statistically invalid controlled trial.

Finally, when no statistically significant differences in efficacy between intervention conditions are found, this will not be interpreted as no difference in reality. It is possible that a treatment form is given insufficient opportunity to be 'effective'. For example, if the reliability of the assessment instrument is used is not investigated, its 'noise' could blur possible differences in efficacy.

EXTERNAL VALIDITY

External validity has to do with generalizing actual results over different patients, circumstances, measurement procedures, sequence of treatment conditions and non-specific parts of the treatment form. If intervention studies are judged as statistically and internally valid, the generalizability of results could, in principle, be established by using estimation theory, which is based on measuring random samples from well-described populations. In rehabilitation research, however, it is impossible - in practice if not principle - to draw random samples from relevant populations (such as 'all patients with hemiplegia after stroke'). It appears, that one is often left with 'pattern recognition' in order to reach some firm ground as to generalizability. Here, the standard procedure is meta-analysis, which tries to establish invariance of results over the different sources of variance by calculating summary effect sizes (see Hedges & Olkin, 1985). In order to reach some firm ground as to generalizability, it is proposed that the criterion for acceptance should be that a statistically and internally valid result be replicated in at least three independent studies: the first two studies being needed to start recognizing a pattern, the third to confirm (or falsify) this pattern.

DISCUSSION

The analysis of actual intervention in the rehabilitation of stroke patients, reveals a number of difficulties, out of which "ignorance of the natural history of individual cases" (Basmajian & Gowland, 1987), is only one. It has been argued, however, that some of these difficulties can be overcome, indeed, have been overcome. Within each domain of stroke rehabilitation, intervention studies can be categorized and discussed with respect to the type of experimental control used (see Wagenaar (1990) for more detailed information), that is:

1) Randomized controlled trials (so-called 'true-experiments') including between-group studies in which patients are distributed randomly among two or more treatment conditions, and ITS experiments involving one patient or a small group of patients in which two or more intervention phases with randomized intervention phases and/or phase-lengths are applied. 'Randomization' decreases the possibility that changes following treatment be attributed to initial characteristics of the patient (selection bias) and/or environmental circumstances (contamination). It is, however, possible that non-specific parts of the treatment have their own effects (confounding). Hence, valid true-experiments should include a sufficient placebo condition.

2) Controlled studies which are similar qua design to true-experiments but lack randomization (so-called 'quasi-experiments'). In quasi-experimental group studies, a satisfactory control for selection bias and contamination is only obtained if patients are matched beforehand with respect to their relevant patient characteristics. Valid quasi-experiments should, also, include a sufficient placebo-condition.

3) Studies without experimental control (so-called 'pre-experiments'), i.e.: group studies without a control group; single case studies involving one patient under only one or two non-repeated intervention conditions; and single case studies replicated on different patients including only one condition.

The statistical procedure used, needs to have been described and p-values reported, in order that a judgment can be made as to whether or not the result obtained could be due to chance. When this information is missing or inaccurate, the intervention study is regarded as statistically invalid. Furthermore, from a group study, in which the gains within each group are separately analyzed without statistically comparing the gains of all groups involved, no valid conclusions can be drawn with respect to differential efficacies. The statistical analysis should compare the gains of all groups or intervention phases involved in the study.

In order to reach some firm ground as to external validity or generalizability of treatment effects, it is suggested that the criterion for acceptance should be that a statistically and internally valid result be replicated in at least three independent studies: the first two studies being needed to start recognizing a pattern, the third to confirm (or falsify) this pattern.

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APPENDIX C

**SUGGESTED OUTCOME MEASURES
TO CONSIDER FOR USE IN STUDIES OF ORTHOTIC INTERVENTION AFTER STROKE**

Extracted From: S. Lennon, V. Pommeroy "Outcome measures for orthotic intervention in stroke rehabilitation"
PPS 256

Outcome measure	Measurement
Impairment	
Muscle activation Movement analysis Kinetic analysis Motricity Index ⁶³ Dynamometry Berg Balance Score ^{3,64} Functional Reach ³ Step test ⁵⁶ Visual Analogue Scales Chedoke McMaster ⁴⁸ Instrumented walkways In-shoe pressure systems	EMG electrodes Joint motion, co-ordination of joints/segments Forces, static/dynamic balance Muscle power Torque around a joint Balance during activity Balance during activity Single Limb Stance balance Pain/Comfort Composite impairment Tempo-spatial gait parameters Foot forces during functional activity
Function	
Action Research Arm Test ^{3,65} Box & Block test ⁶³ Frenchay Arm test ⁶⁶ 5 meter walk ⁵⁴ 10 meter walk ⁴⁹ 6 minute walk ⁴⁹ Timed get up & go ³ Functional Independence Measure ³ Fugl-Meyer Assessment ^{73,67,68} Motor Assessment Scale ⁶⁹ Functional Mobility Scale Modified Rivermead Mobility Index ⁵⁹ Rivermead Mobility Index ⁵⁸	Functional use of the upper limb Manual Dexterity Arm function Gait velocity Gait veleocity Walking endurance Movement & Function Mobility Mobility
Other	
Canadian Occupational Performance Measure ⁷⁰ Falls Efficacy Scale ⁷¹ Goal Attainment Scaling ⁷²	

COMPENDIUM

State of the Art and Key Review Papers

STROKE – UNDERSTANDING THE PROBLEM (S1)

Tom Skyhøj Olsen, MD, PhD

INCIDENCE, PREVALENCE AND COST

Stroke is a serious and common disease. According to WHO stroke is the second most common cause of death worldwide and the third most common cause of death in the industrialized world (1). More than 5.5 million died because of a stroke in 1999 and 2/3 of these deaths occurred in the less developed part of the world (2). Within the first month after a stroke app. 20 - 25% have died (3,4) and within the first year this figure has increased to 30-40% (5). After 5 years only 1/3 of the stroke patients are alive (6). Stroke is thus comparable to cancer in rate of death.

The severity of the stroke disease appears from the high number of disablement caused by stroke; stroke is one of the most frequent causes of long-term disability in the adult population and as much as 15% need nursing home care after a stroke (5).

Stroke is common and affects app. 2-3 per 1000 per year in a population (3,4). That means that 1 in every 7 in a population may anticipate a stroke and because of the strong association with age 1 in every 5 in a population more than 50 years of age will suffer a stroke (4). App. 10% of the strokes are due to haematomas, 5% are due to subarachnoid haemorrhage and 85% are ischemic strokes (3). Recurrence is common. Between 10% and 15% have a recurrent stroke within the first year and in the subsequent years it is 5 to 6% (7). Hence, in an unselected stroke population app. 20% have experienced two or more strokes (5,6).

Although stroke afflicts all ages it is unquestionably a disease of the elderly. While the overall prevalence rate is 6-8 per 1000 persons it is 40-70 per 1000 persons \geq 65 years of age (3). Mean age of first stroke is 70 years in men and 75 years in women (5,6). In The Copenhagen Stroke Study app. 70% of the patients were more than 70 years of age and 35% were more than 80 years of age (Figure 1). In this study stroke affected men twice as often as women and in the years up to 60 or 70 2/3 of the patients are men. Later on – due to the better survival – the majority of strokes are in women (Figure 2).

Stroke is a costly disease. In Europe app. 5% of the total expenditures for hospital service are due to treatment or rehabilitation of patients with stroke (9). This makes stroke the costliest of all diseases in hospitals, more costly than heart diseases, cancer, etc. The lifetime costs of stroke is estimated at between 60 000\$ and 230 000\$ (10). In US the projected cost of stroke 2003 is 59 billion \$; this figure includes 12 billion \$ for nursing home costs (11). The total cost of stroke care inevitably will rise in real terms by 30% within the next 20 years (12). The reason why stroke is so costly compared to other diseases is first of all the use of bed days. Length of stay of an average stroke patient is 5-6 times longer than that of average medical patients, i.e. stroke patients are about 4-5 weeks in hospital (5,6). In Denmark 10% of the hospital beds in the medical sector are used for treatment and rehabilitation of patients with stroke

and in UK 20% of all acute hospital beds are occupied by stroke patients (13,14).

Stroke is nearly always the consequence of another disease process. The majority of stroke patients therefore suffer from other diseases most often diseases caused by atherosclerosis: According to The Copenhagen Stroke Study 1/5 had atrial fibrillation, 1/5 had diabetes, 1/10 had peripheral atherosclerosis with claudication, 1/4 had ischemic heart disease and 1/3 had hypertension. Besides that 1/5 had already suffered one or more strokes (Figure 3) (5,6). Stroke treatment; therefore, involve treatment of a broad variety of diseases of internal medicine.

The burden of stroke inevitably will increase in the years to come. Overall, there is a trend towards stabilising or increasing stroke incidence in the elderly population (3) but due to the increase of lifetime expectation the percentage of elderly people within the population will grow continuously. Hence, due to this growth the number of stroke are expected to increase by 20% year 2010 (15) and the number is expected to be more than doubled at 2050 (16).

EPIDEMIOLOGY OF STROKE-RELATED DISABILITY

The epidemiology of stroke-related disability – physical as well as cognitive - has been investigated in detail in The Copenhagen Stroke Study. This stroke study was established in 1991 and included patients in a 25 months period until 1993. The study is a prospective, consecutive and community-based study of 1197 completely unselected acute stroke patients, admitted to a 63-bed stroke unit exclusively serving a catchments area of app. 240 000 people in the City of Copenhagen. In this area the hospitalisation rate for stroke is high - more than 90% of the stroke population is hospitalized. All acute treatment, work-up and rehabilitation were performed within the stroke unit, regardless of age, stroke severity, and the patient's condition before stroke. A five-year follow-up of the patients has been performed and a ten-year follow-up is now ongoing.

Rehabilitation in this cohort was performed in accordance with the principles of Bobath (17). Rehabilitation took place in a multidisciplinary team. The rehabilitation program was individualized according to the needs of the patient, and weekly team conferences were held to evaluate the progress of the patient and to determine therapeutic goals. Patients were not discharged until the team considered further in-hospital improvement to be unlikely.

In all patients stroke severity was measured on admission and weekly during hospital stay using the *Scandinavian Stroke Scale* (0-58) (18) and the *Barthel score* (0-100) (19). A follow-up was performed after 6 months, 5 and 7 years. The risk factor profile was established in all patients. Mean age of the patients was 74.3 years, 46% were males and the average length of stay was 37 days. Twenty-one percent of the patients died during hospital stay, 64% were

discharged to their own home after rehabilitation and 15% were discharged to a nursing home (5).

Neurological impairment

In the Copenhagen Stroke Study cohort 19% of the strokes were classified as very severe (SSS 0-14), 14% as severe (SSS 15-29), 26% as moderate (SSS 30-44), and 41% as mild (SSS 45-58) (20). About 25% of the patients had no initial disability of everyday life basic activities. Single neurological modalities were affected as follows: 24% had reduced consciousness on acute admission, 43% had decreased orientation, 48% had facial paresis, 70% had paresis of the hand, 69% had paresis of the arm, 65% had leg paresis, 38% had aphasia, 23% had neglect, 21% had anosognosia and apraxia was seen in 10% in the very acute state of the stroke (Figure 4).

In survivors, neurological impairment after completed rehabilitation was still severe or very severe in 11%, moderate in 11%, mild in 47%, and 31% had achieved normal neurological function (20).

Neurological impairment after completed rehabilitation was strongly related to the initial impairment. No or only mild impairment was achieved in 95% of patients with mild stroke, in 80% of patients with moderate stroke, in 40% of patients with a severe stroke and in 20% of patients with initially very severe stroke (20).

Neurological recovery

Rate of neurological recovery was measured as the time from stroke onset to the time when best SSS score was obtained, and it was noted in all patients by examination of the weekly scores. In total 95% of the patients reached their best neurological level within 11 weeks. The rate of neurological recovery depended on initial stroke severity: In mild strokes neurological recovery occurred within 6 weeks. In moderate strokes it occurred within 10 weeks, in severe strokes it was within 15 weeks and in patients with the most severe strokes neurological recovery occurred within 13 weeks from stroke onset. However, best neurological score was reached in 80% of all patients already within 1 month; within 2 weeks in patients with mild stroke, within 6 weeks in patients with moderate stroke, within 9 weeks in patients with severe strokes, and within 10 weeks in 80% of the patients with the most severe strokes (21).

Functional disability

The ability to perform basic *activities of daily living* (ADL) initially was reduced in three out of four patients with stroke. Most often affected was the ability to transfer, dress, and walk. In the acute state personal assistance was required in 2/3 for transfer, in 1/2 for dressing, grooming and feeding, in 2/3 for toileting and in 2/3 for walking. Half of the patients were bowel and/or bladder incontinent (Figure 4). After completed rehabilitation the group with moderate and severe disability was reduced from 50% to 25%, and the group with mild or no disability had increased from 50% to 75% (20).

In survivors 20% of those with initially very severe strokes had no or only mild functional disability after completed

rehabilitation compared with 35% of those with severe strokes and 68% of those with moderate strokes. In patients with mild strokes 68% had no disability in ADL functions after completed rehabilitation (20).

Functional recovery

In general functional recovery was completed within 3 months of stroke onset. Speed of recovery was, however, directly related to stroke severity (Figure 5): Patients with mild strokes recover within 2 months, patients with moderate strokes within 3 months, patients with severe strokes within 4 months, and patients with the most severe strokes have their functional recovery within 5 months from onset (21). Only 9 of the 1197 patients in The Copenhagen Stroke Study experienced functional recovery later than 5 months after the stroke. However, best function was reached in 80% of all patients already within 3 weeks in patients with mild stroke, within 7 weeks in patients with moderate stroke, and within 12 weeks in 80% of the patients with severe and very severe strokes (21).

Walking function

Impaired walking function greatly contributes to functional disability, and improvement in walking function is the single goal most often stated by patients with stroke. In The Copenhagen Stroke Study initial walking function was impaired in 63% of the patients. Of the patients 51% had initially no walking function, 12% could walk with person assistance and 37% could walk independently. After completed rehabilitation 21% had died, 18% had still no walking function, 11% could walk with assistance and 50% had independent walking function. Among survivors 66% achieved independent walking function and 22% were still left with no walking function after completed rehabilitation (Figure 6)(22).

Only 15% of the patients with no walking function gained independent walking function. Only 6% with initial leg paralysis achieved independent walking function compared with 21% of the patients with initially severe paresis, 28% of those with moderate paresis, 66% of those with mild paresis, and 78% of the patients with no leg paresis (22). In total 95% of the patients had reached their best level of walking function within 11 weeks from stroke onset. In patients with no, mild, or moderate leg paresis a valid prognosis of walking could be made within 3 weeks from onset, in patients with initially severe paresis or total paralysis this was possible within 6 weeks. These results correspond well to the findings of others (23, 24). Degree of initial impairment of walking function and the severity of leg paresis were determinants for final walking function and rate of recovery. Only 10% of patients with initial leg paralysis regained independent walking function. In these patients ADL function was high and leg strength improved quickly in the first week (25).

Upper extremity function

Upper extremity dysfunction greatly contributes to functional disability after stroke. In The Copenhagen Stroke Study cohort 69% of the patients had upper extremity

paresis on admission. The paresis was severe in 46% of the patients, and it was mild or moderate in 54% of the patients (26).

Initially, 55% of the patients had reduced upper extremity function. Of the patients, 45% had normal upper extremity function, 24% had partial function, and 31% had no function. After rehabilitation 60% had gained normal function, 12% had partial function, 7% still had no function, and 21% had died (Figure 7) (26).

Recovery of upper extremity function was closely related to the degree of upper extremity paresis on admission. In patients with severe paresis or paralysis on admission, 73% had initially no function of the upper extremities, 22% had partial function, and 5% had full function. After completed rehabilitation 45% of these patients had died, 20% had still no function, 24% had gained partial function, and 11% had reached full function. In patients with initially no or only partial function of upper extremities, 57% of the survivors improved to an upper category (26).

In patients with initially mild or moderate upper extremity paresis, 13% had initially no function, 31% had partial function, and 56% had full function of the upper extremities. After completed rehabilitation 77% had gained full function, 10% had partial function, 5% had no function and 8% had died (26).

In total, best upper extremity function was reached by 80% of the patients within 3 weeks and by 95% of the patients within 9 weeks. Corresponding weeks in patients with initially mild or moderate paresis were 3 and 6 weeks, and in patients with severe paresis or paralysis it was 6 and 11 weeks, respectively (26). These results of The Copenhagen Stroke Study correspond well with the findings of others (23,24).

Bowel and bladder functions

Urinary and faecal incontinence occur frequently in stroke and contribute significantly to the disablement. Initially, almost half of the stroke patients in The Copenhagen Stroke Study had urinary and/or faecal incontinence. There was a large overlap between patients with urinary and faecal incontinence. Of the patients 84% with urinary incontinence had also faecal incontinence, and 98% of the patients with faecal incontinence had also urinary incontinence.

On admission 36% were fully urinary incontinent and 11% had partial urinary incontinence. After completed rehabilitation 15% of the survivors were still fully incontinent and 13% had partial incontinence.

On admission 40% had faecal incontinence; 34% were fully incontinent and 6% had partial incontinence. After completed rehabilitation 12% of the survivors was still fully faecal incontinent and 6% had partial incontinence.

A multiple logistic regression model showed that significant risk factors for urinary and faecal incontinence were age, stroke severity, diabetes and other disabling diseases (27).

Aphasia

Aphasia is a common and feared symptom in stroke and it is considered a major disability by stroke patients as well

as their relatives. Incidence of aphasia in The Copenhagen Stroke Study was 38%. Of the patients 12% had mild aphasia, 6% had moderate aphasia and 20% had severe aphasia. A further 6% had speech disturbance considered to be dysarthria (28).

Of the patients, 31% with aphasia died during hospital stay. After completed rehabilitation 44% of the survivors with initial aphasia had gained normal language function. In patients with severe aphasia on admission 47% died, 18% still had severe aphasia, 10% had moderate aphasia, 13% had mild aphasia, and 12% had gained normal language function after completed rehabilitation. In patients with initial moderate aphasia the corresponding figures were 18%, 3%, 8%, 30% and 41%, and in patients with mild aphasia it was 10%, 4%, 4%, 26% and 56% respectively. In total, best language function was reached by 84% within 2 weeks from stroke onset. In patients with mild aphasia on admission 80% had reached their best language function within 1 week and 95% had reached it within 2 weeks. In patients with moderate aphasia it was 4 and 6 weeks, and in patients with severe aphasia best language function was reached within 3 weeks in 80% and within 10 weeks in 95% of the patients (28).

Anosognosia, hemineglect and apraxia

Anosognosia is denial or unawareness of disease. It was seen in 21% of the patients in The Copenhagen Stroke Study; 36% in the right and 9% in the left hemisphere (29).

Hemineglect is the failure to report, respond, or orient to novel or meaningful stimuli presented to the side opposite a brain lesion, when this failure cannot be attributed to either sensory or motor defects (30). It was seen in 23% of the patients in The Copenhagen Stroke Study; 42% in right hemisphere stroke and 8% in left hemisphere stroke.

Apraxia is disturbance of action with real objects as well as disturbance of symbolic and imagined actions. It was seen in The Copenhagen Stroke Study in 7% of the patients; 10% in left hemisphere stroke and 4% in right hemisphere strokes (31).

Rate of recovery in these cognitive disturbances are only sparsely studied and described.

Many other symptoms and impairments contribute to the disablement of the stroke patient: Central pain (8-9%) (32), epilepsy (3-4%) (33), depression (30-50%) (34), emotional incontinence (10-15%) (35), fatigue (40%) (36), vascular dementia (15-30%) (37), and many more.

UNDERSTANDING THE PROBLEM

Understanding the problem of stroke is to understand the burden of stroke laid on the stroke victim, the relatives and the society. It is to understand the challenge this disease is to the health care system. Stroke is common – very common and we have to anticipate many more stroke victims as lifetime expectation increases. This predictable future yet hardly realised by society will leave an enormous economic burden the health care system. In the foreseeable future stroke may be “the” major burden on the health care system.

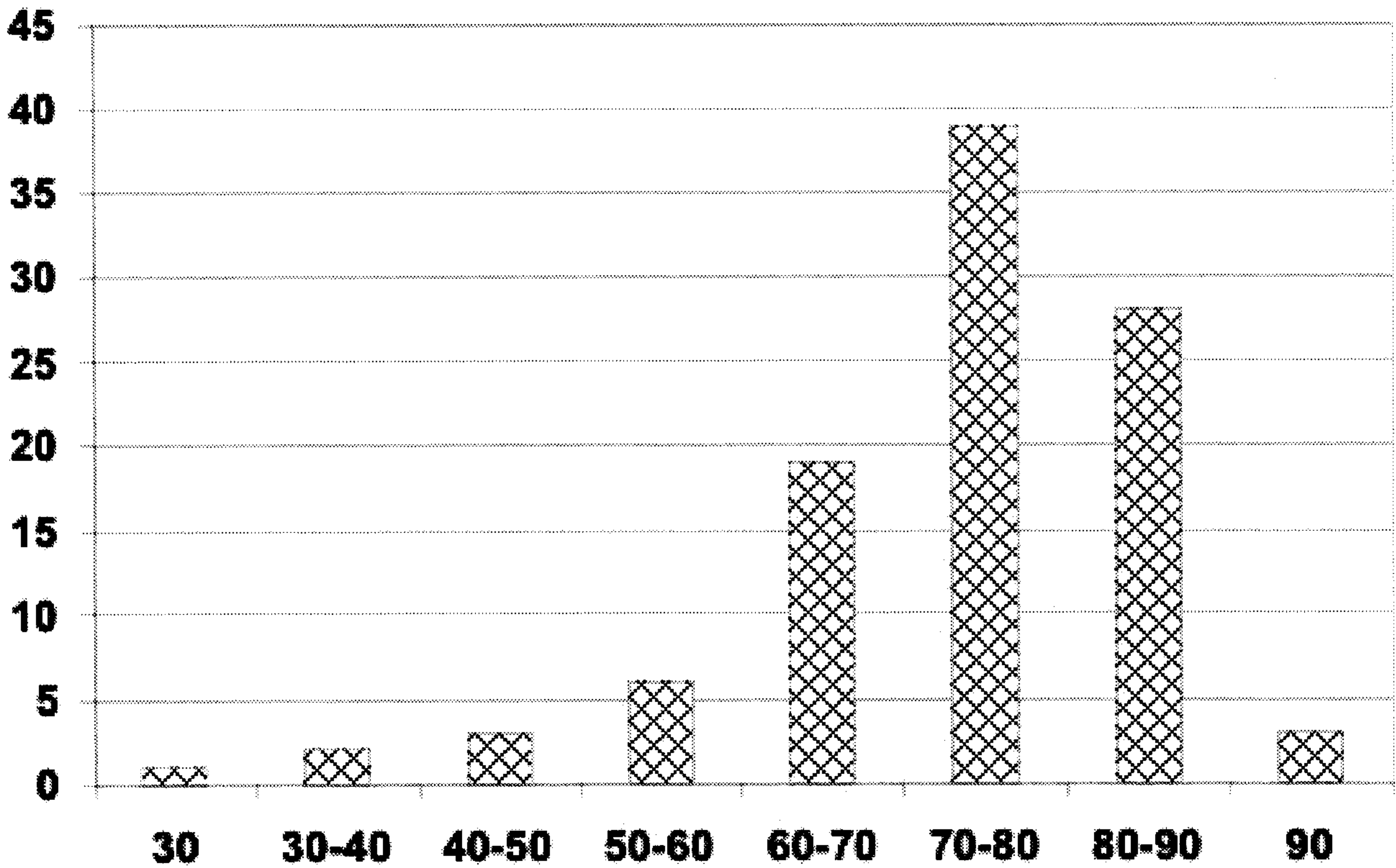


Figure 1. Stroke – age distribution %

Stroke is easily characterized and the symptoms and deficits are usually the same from patient to patient. Nevertheless, every stroke patient is unique and does not look alike. This is a major part of the problem challenging especially

those who treat, takes care of and rehabilitate patients with stroke. Understanding this is an absolute precondition for the success of all our effort.

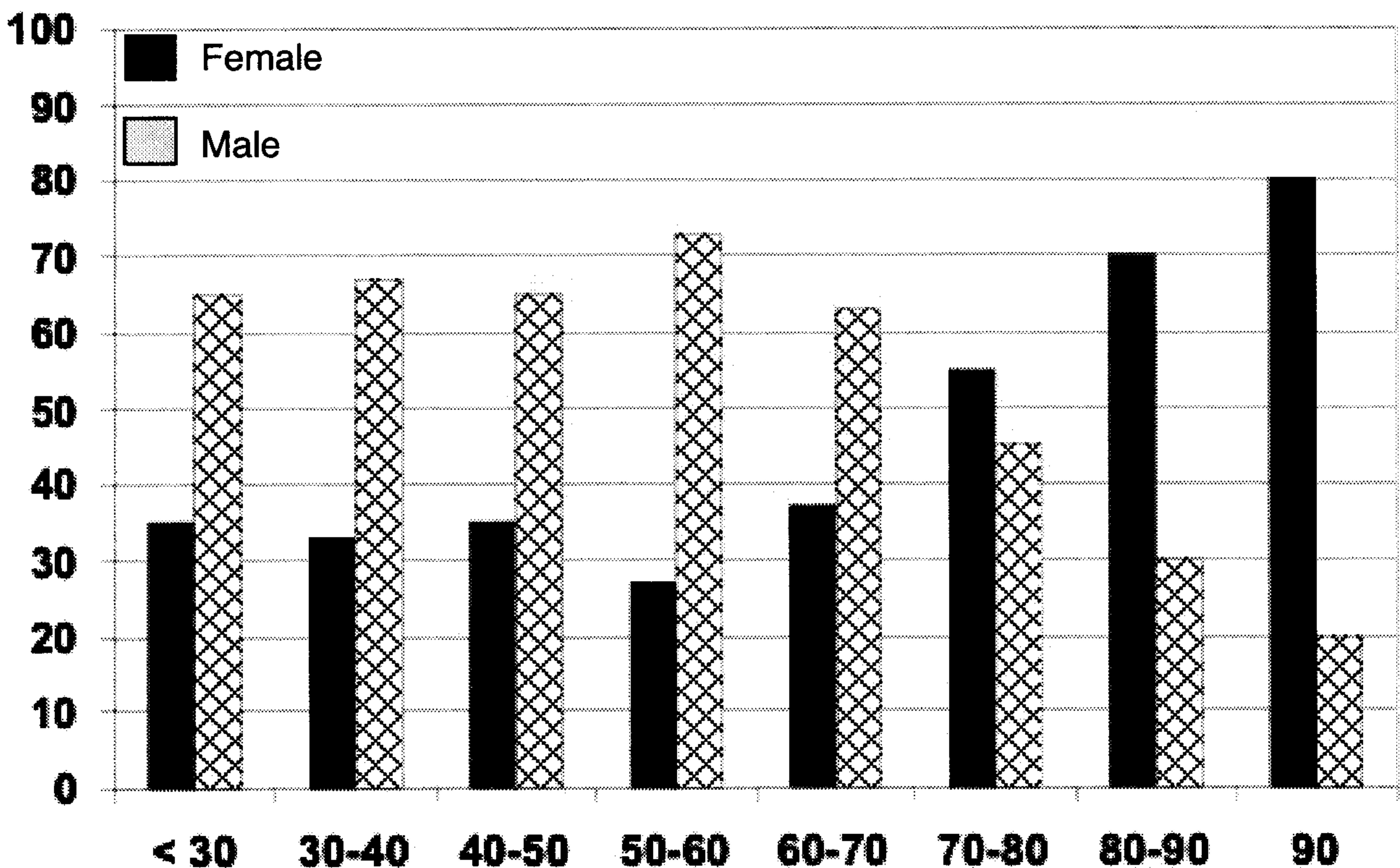


Figure 2 Stroke - age related sex distribution %

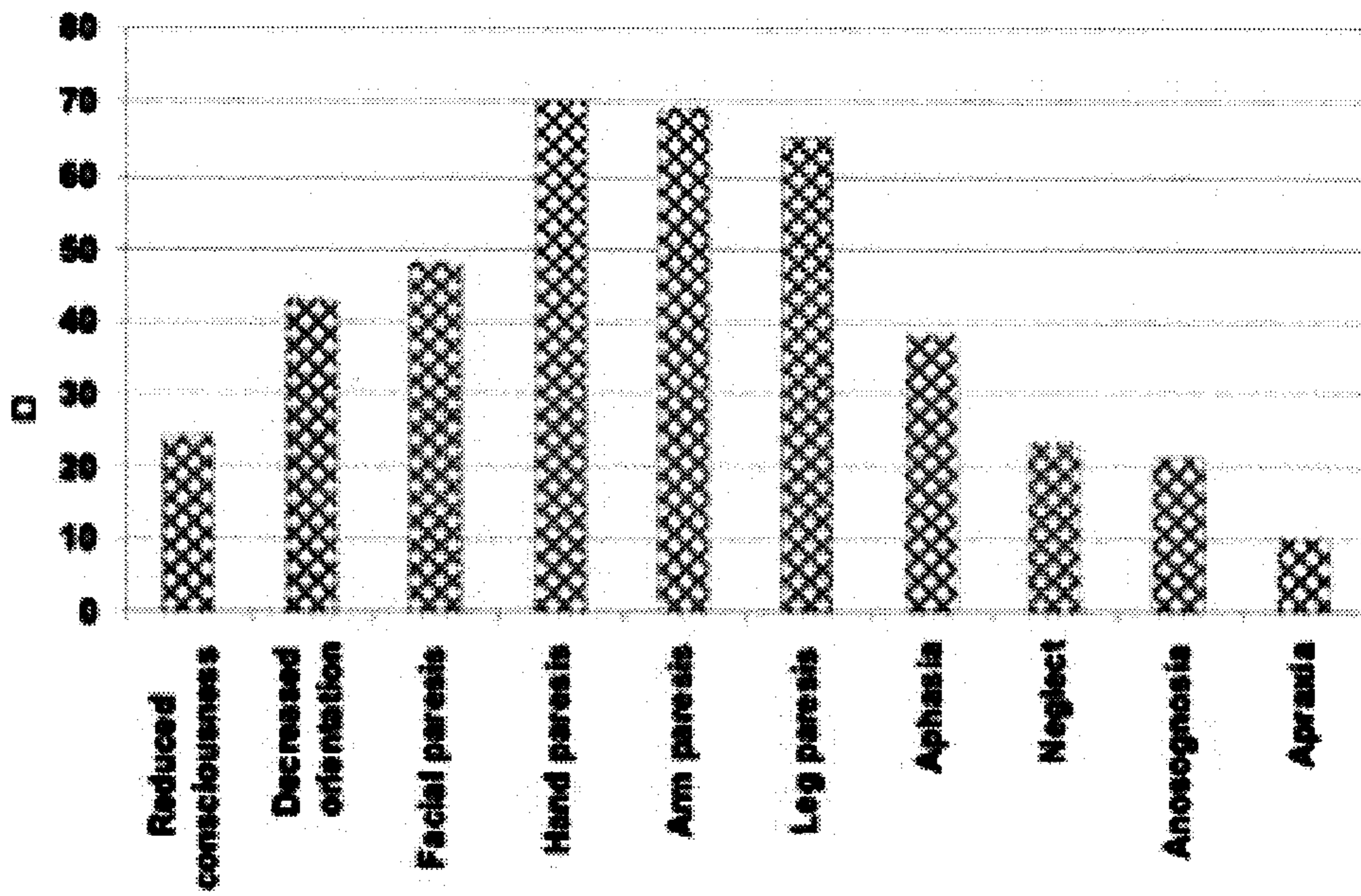


Figure 3. Stroke – affected neurological modalities %

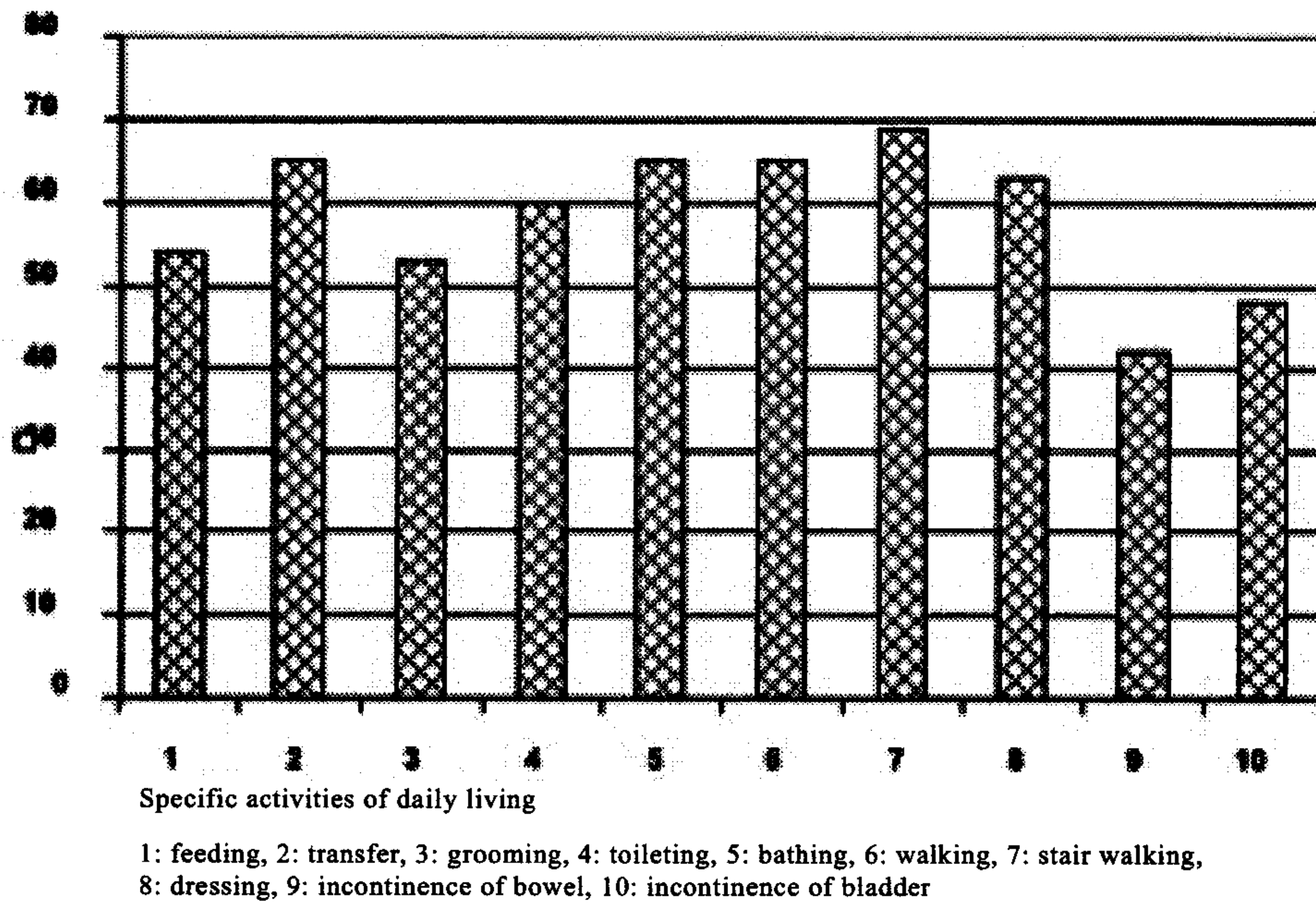


Figure 4. Stroke - % of patients with initial disability

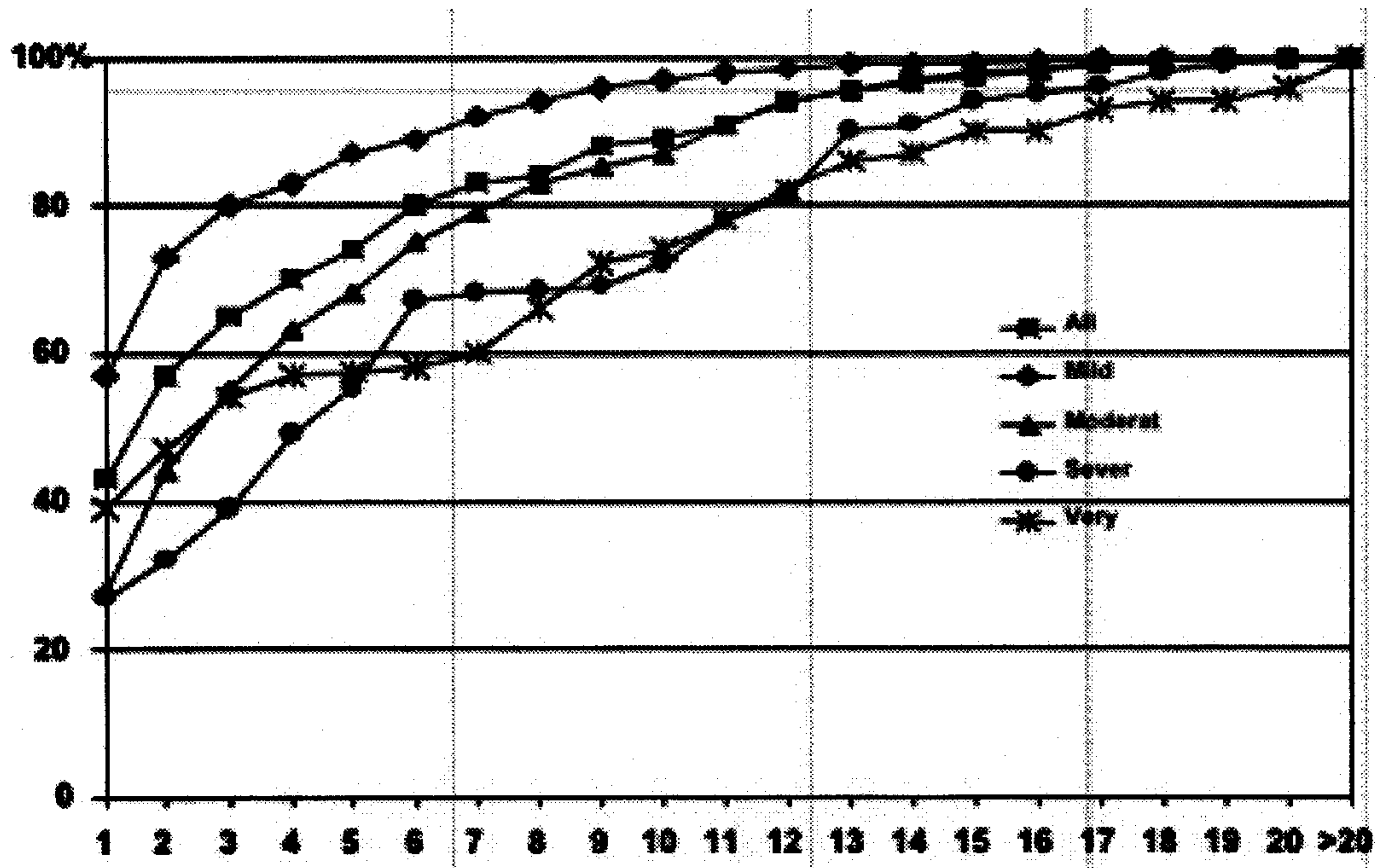


Figure 5. Time course of recovery; cumulated rate of patients having reached best ADL recovery (Barthel Index)

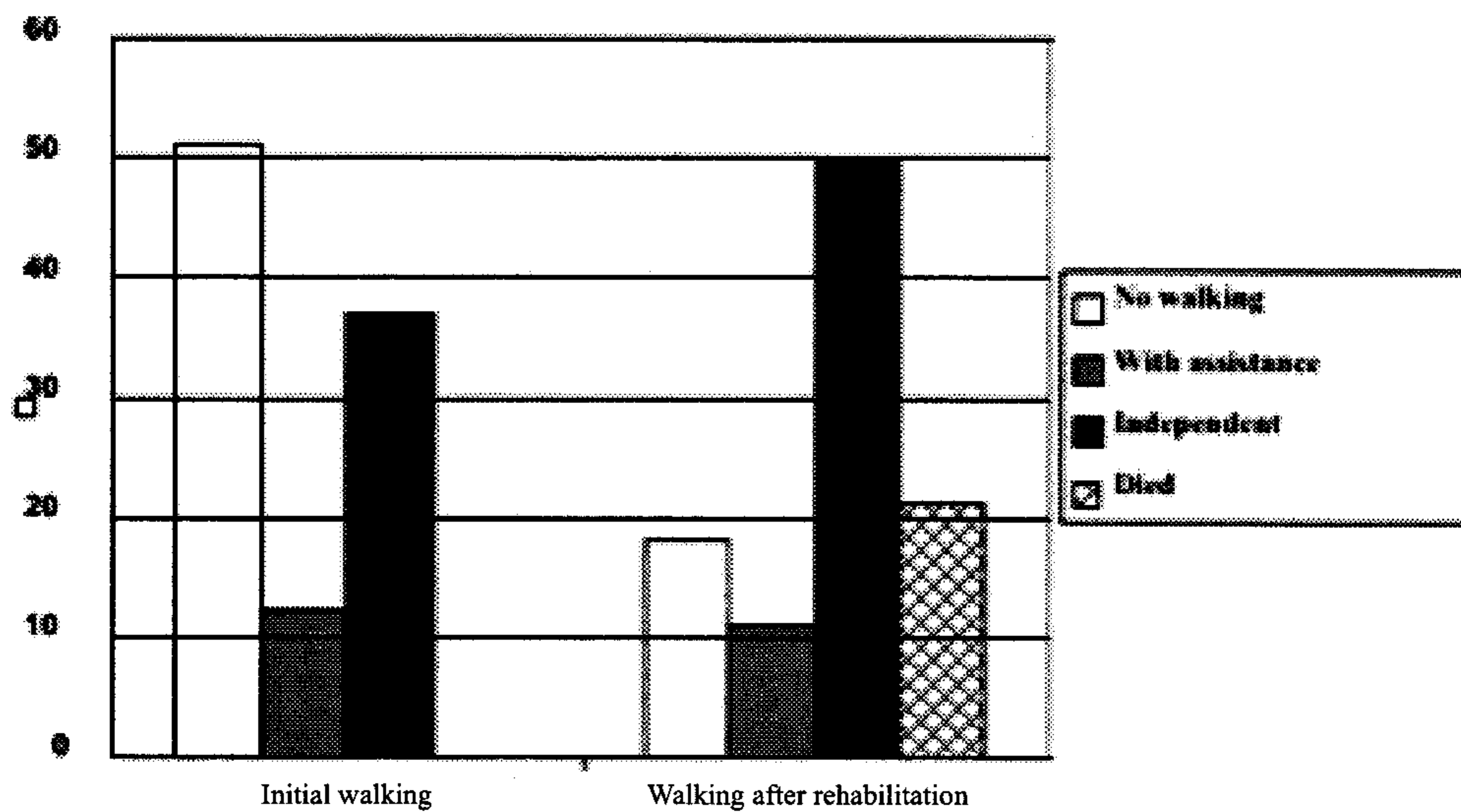


Figure 6

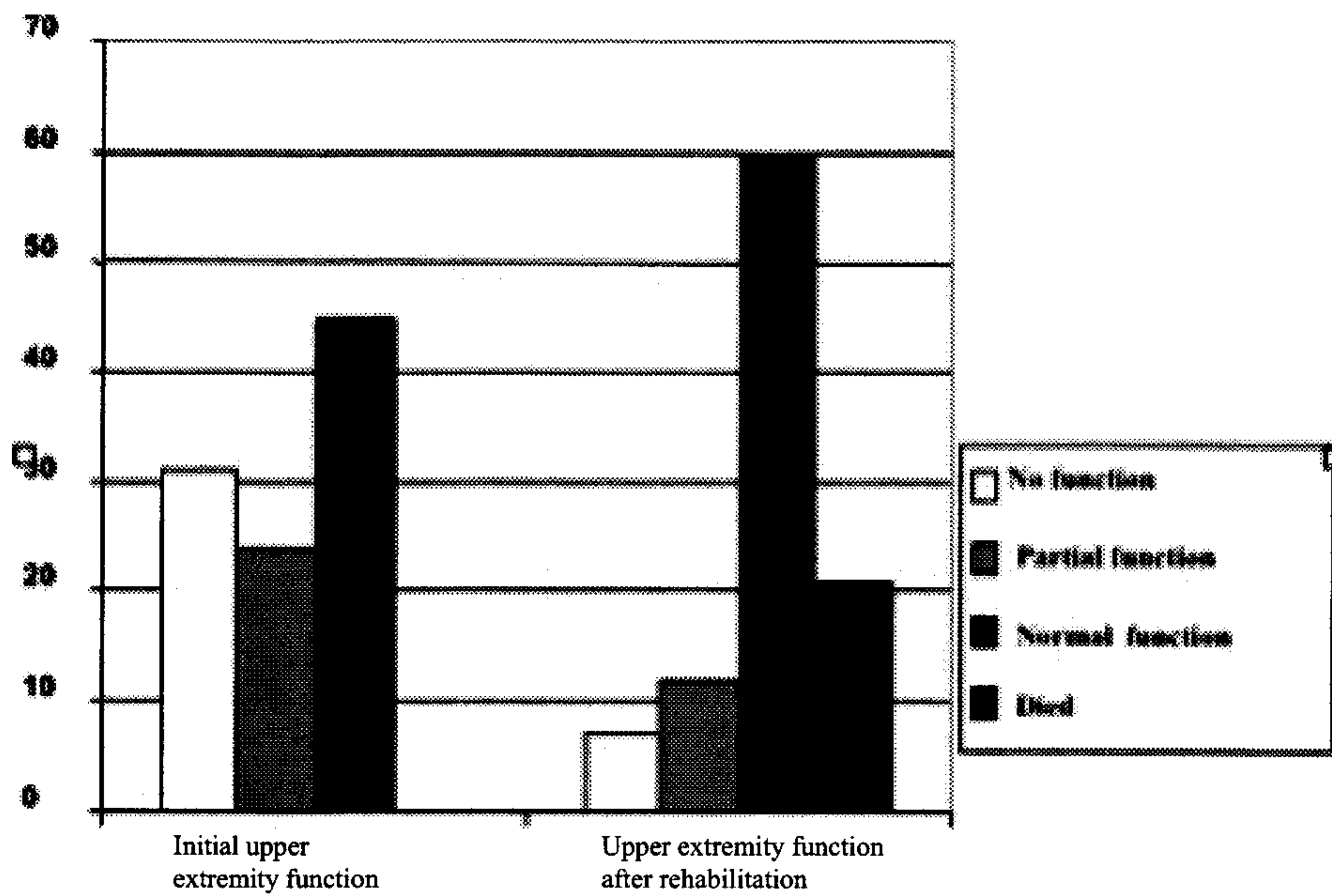


Figure 7 Stroke - upper extremity function%

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CLINICAL AND FUNCTIONAL EFFECTS OF STROKE (S2)

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INTRODUCTION

At the present time there is insufficient information available to the medical community to determine the optimal rehabilitation program based on patient characteristics for individuals who have sustained a stroke. Stroke is a major cause of disablement in many western countries. In the USA, each year 600,000 new cases are reported, with an overall prevalence of about 4,600,000 survivors of stroke in the USA (American Heart Association, 1991; National Stroke Association, 1999). The standardized annual incidence rate for stroke in men and women is approximately 1.74 and 1.96 per thousand, respectively. The risk increases considerably with age, with males having a significantly higher incidence than females for all age groups below 75. About 20% of the stroke patients die within 21 days immediately after stroke. Of those who survived the acute phase (defined as the first 3 weeks post stroke), about 40% remain dependent upon other persons for their activities of daily living (ADL), 25% are hospitalized or transferred to a nursing home, and almost 70% are unable to return to work (Wagenaar & Kwakkel, 1999). Although most patients regain their walking ability, 30% to 66% are no longer able to use the affected arm (van der Lee et al., 1999). Perceptual deficits (e.g., hemineglect) are often part of the hemiplegic syndrome, and tend to hamper the recovery of motor behavior. In addition, speech deficits, depression and neuropsychological disorders such as dyspraxia, are often observed in stroke patients, leaving rehabilitation practitioners with a bewildering complexity of impairments and disabilities (Wade & Langton-Hewer, 1989).

About fifteen years ago mixed messages with regard to the existing evidence to support the efficacy of rehabilitation on the functional recovery after stroke were stated in the literature. For example, Basmajian and Gowland (1987) claimed that one needs to define the natural history of recovery, and classify its various pattern over time. The heterogeneity of the stroke population appeared to be a major obstacle in intervention studies the effects of stroke rehabilitation. The establishment of such a classification system could be the key to better research and better care of patients. Dobkin (1989) stated that convincing evidence concerning the therapeutic usefulness of stroke rehabilitation does not yet exist. Ernst et al. (1990), however, indicated that evidence available suggests that it does not matter which form of treatment is chosen and that any of the available approaches in physical and occupational therapy will improve the patient's functional status, although spontaneous neurological recovery appears to account for most of the improvement in functional ability. In their critical review of 165 intervention studies on stroke rehabilitation Wagenaar and Meijer (1991a&b) reported the following patterns amongst studies: 1) specialized stroke (rehabilitation) wards reduce mortality and improve ADL, 2) intensity of rehabilitation is perhaps an important component of specialized stroke

care, 3) no significant differences between different (traditional) neuro-rehabilitation approaches were found, and 4) reported effects are limited to the impairments and functions trained and show hardly any generalization to other parameters (see also Wagenaar et al., 1992). Since then a large number of intervention have been published in the literature and, hence, the aim of this paper is to evaluate the current state of the art on the effect of stroke rehabilitation and determine to what extent intensity and delivery setting of rehabilitation practice as well as specific rehabilitation methods affect the functional recovery of patients who have had a stroke.

EXPERT CARE

During the past 40 years, the idea has gained ground that concentrating stroke patients in specialized stroke units in hospitals or rehabilitation centers is of benefit to the patient. In general, these stroke (rehabilitation) wards are run by a coordinated team of professional medical, nursing and therapy staff, which is expert in managing, for example, the rehabilitation process of patients after stroke (e.g., Garraway, 1982; Wade & Langton-Hewer, 1989). This raises the question 'In how far is expert care effective? In a meta-analysis (summarizing the outcome of 16 randomized controlled trials (RCTs)) on the effects of organized stroke unit care Langhorne et al. (1993) found a reduced mortality, reduced institutionalization, and reduced dependency in activities of daily life compared to conventional care (effect size 0.71 +/- 0.11). For every 100 patients, an extra five patients returned home in an independent state, providing more evidence for benefits of organized in-patient multi-disciplinary rehabilitation (Langhorne & Duncan, 2001). Although expert care is regarded as the defining characteristic of the stroke ward, it is still unclear which factors within expert care contribute to outcomes, i.e.: team care, active family participation, special staff education, early start of treatment, and/or intensity of treatment.

INTENSITY OF STROKE REHABILITATION

The results of a number of controlled studies suggest that an early start of intensive treatment is an important part of expert care (e.g., Wade & Langton-Hewer, 1989; Wagenaar & Meijer, 1991a&b). In their research synthesis on the effects of intensity of stroke rehabilitation after stroke, Kwakkel et al. (1997) calculated the summary effect sizes of nine controlled studies (N=1051). The meta-analysis demonstrated a small, but statistically significant summary effect size for ADL (0.28 +/- 0.12; see also Langhorne et al., 1996). A lower summary effect size (0.19 +/- 0.17) was found for studies in which experimental and control group were treated in the same setting compared with studies in which the two groups of patients were treated in different settings (0.40 +/- 0.19). Variables defined on a neuromuscular level (0.37 +/- 0.24) revealed larger summary effect

sizes than variables defined on a functional level (0.10 +/- 0.21). Weighting individual effect sizes for the difference in amount of rehabilitation between experimental and control groups resulted in larger summary effect sizes for ADL and functional outcome parameters.

Critically reviewing these controlled trials, Kwakkel and his colleagues (1997) found that insufficient contrast in the amount of rehabilitation between experimental and control conditions, organizational setting of rehabilitation management, lack of blinding procedures, and heterogeneity of patient characteristics were major confounding factors. In their systematic review of RCTs focused on the effects of different amounts or duration of exercise therapy for arm function in stroke patients, Van der Lee et al. (2001) concluded that more intensive exercise therapy appears to be beneficial. Differences in design made it impossible to combine the effect sizes of the individual studies. However, six out of the thirteen included studies reported positive findings on an arm function test. This corroborates the results of a meta-analysis by Ottenbacher and Janell (1993) combining the findings of 36 studies on the effects of stroke rehabilitation wards as well as different methods of rehabilitation in one summary effect size of 0.4 magnitude. They found that programs with focused stroke rehabilitation may improve functional performance for patients who have sustained a stroke.

The findings of these research syntheses provide evidence that an early start of high intensity of stroke rehabilitation improves recovery in impairments, functional limitations, and disabilities. However, many of the intervention studies included in the meta-analyses were hampered by methodological shortcomings. Therefore, Kwakkel et al. (1999) investigated the effects of different intensities of arm and leg rehabilitation training on the functional recovery of ADL, walking ability, and dexterity of the paretic arm in a single blind randomized controlled trial. Within 14 days after stroke onset, 101 severely disabled patients with a primary middle-cerebral-artery stroke were randomly assigned to: 1) a rehabilitation program with emphasis on arm training; 2) a rehabilitation program with emphasis on leg training; or 3) a control program in which the arm and leg were immobilized with an inflatable pressure splint. The treatment protocols were based on the best evidence for stroke rehabilitation. Arm rehabilitation included functional exercises that facilitated forced arm and hand activity such as leaning, punching a ball, grasping, moving objects. The key elements in leg rehabilitation were sitting, standing and weight bearing exercises during standing and walking, with an emphasis on achieving improved gait velocity (if possible by means of treadmill). If treatment at a functional limitation level was not possible, strengthening exercises for arms and legs were promoted. Each treatment was applied for 30 minutes, five days a week during the first 20 weeks after stroke. In addition, all patients underwent a basic rehabilitation program. ADL was assessed by means of the Sickness Impact Profile and Barthel Index, walking ability by means of the Functional Ambulation Categories and walking speed, and dexterity of the paretic arm by means of the Action Research Arm test at 6, 12, 20, and 26

weeks post stroke. Intention-to-treat analysis was applied. It was found that greater intensity of leg rehabilitation significantly improves ADL, walking ability (compared to arm rehabilitation and control program), and dexterity (compared to control program), whereas the arm rehabilitation group showed a significant improvement in dexterity compared to the control group. The improvements in ADL and walking ability were already significant after 6 weeks of leg rehabilitation, whereas the improvement in dexterity was significant after 12 weeks of arm rehabilitation. These findings not only indicate that higher intensity of stroke rehabilitation speeds up functional recovery, but also strongly suggest that an early start of intensive rehabilitation benefits the patients who have had a stroke. The improvement in walking ability was also reflected in a significant improvement in comfortable and maximal walking velocity, whereas no differences in efficacy were obtained for the coordination of walking. No significant differences between the three conditions were found during follow-up assessments 50 weeks post stroke. However, it should be noted that the patients were not treated according to the abovementioned protocols between 20 and 50 weeks post stroke. Hence, it remains open to further investigation whether higher rehabilitation intensity in the chronic stage after stroke can facilitate functional recovery.

More detailed (regression) analysis of the recovery patterns by Kwakkel and his colleagues (Kwakkel et al., 2000) revealed that the Barthel Index score, degree of initial sitting balance, and level social support assessed within the first five weeks post stroke explained 56% of the total variance of the Barthel Index score measured six months post stroke. The Barthel Index score and the degree of initial sitting balance were also moderate predictors for walking ability assessed six months post stroke, explaining 41% of the variance in walking ability. More than 61% of the total variance of dexterity at six months post stroke was explained by motor function tests (i.e., Fugl-Meijer and Motricity Index scores) and the Barthel Index score obtained within five weeks post stroke. After the fourth week no change in probabilities of prediction dexterity was found, suggesting that outcome of dexterity is to a large extent determined by recovery within the first 4 post stroke weeks; no emergence of arm synergies at 4 weeks is associated with poor outcome at 6 months (see also Kwakkel et al., 2003; Wagenaar et al., 1990). The latter result supports findings of a number of studies (Twitchell, 1951; Newman, 1972; Skilbeck et al 1983; Heller et al 1987; Sunderland et al 1989) indicating that the absence of a measurable arm and grip function within about one month post stroke is an important determinant of poor functional recovery of the hemiplegic arm. These findings show that indeed spontaneous neurological recovery appears to account for most of the improvement in functional ability after stroke (Ernst et al., 1990).

FUNCTIONAL TRAINING

Although more intensive rehabilitation is associated with better outcomes, optimal forms of occupational, physical and speech/language therapy have not yet been defined. According to Ernst (1990), all the available approaches appear to promote improvement in functional status. Indeed, most studies report differential treatment effects, but these effects are often limited to the activity in which the patient was trained (Wagenaar & Meijer, 1991a&b). Facilitation techniques, inhibition techniques, functional electro-stimulation (FES), and Electro-Myographic (EMG) feedback therapy have resulted in differential effects on parameters defined on the neuromuscular level, but showed few transfer effects to ADLs. For example, in their meta-analysis of four RCTs on the effects of FES Glanz et al. (1996a) found that FES promotes recovery of muscle strength after stroke (0.63 +/- 0.35). However, it remains open to further investigation whether increased strength generalizes to walking ability. Moreland et al (1998) combined the individual effect sizes of three to seven RCTs in a meta-analysis on the effects of EMG feedback therapy to improve lower extremity function after stroke. They reported a significant summary effect size for ankle dorsi-flexion muscle strength (1.17 +/- 0.67). No significant effect sizes were found for gait quality, ankle range of motion during gait, stride length, and walking speed. Glanz et al. (1996b) reported no significant effect sizes for EMG feedback therapy in restoring the range of motion of hemiparetic joints for both lower extremity and upper extremity (see also meta-analysis Moreland & Thomson, 1994).

These findings support the conclusion by Wagenaar & Meijer (1991a&b) that the effects of rehabilitation techniques are very specific. The findings of the meta-analysis by Schleenbaker and Mainous (1993), however, suggest that effects of EMG feedback therapy generalize to functional outcome (e.g., walking ability and dexterity). They reported a summary effect size of 0.81 (+/- 0.31). However, since they included RCTs comparing EMG feedback therapy with a no-treatment control condition, it is impossible to infer that EMG feedback therapy improves functional outcome. Only a small number of studies have found specific effects on functional tasks; for example, Cozean et al. (1988) noted the effect of the combination of FES and EMG feedback therapy applied during sitting and walking on ankle and knee angles during gait; Shumway-Cook et al. (1988) and Winstein et al. (1989) noted the effect of postural sway feedback therapy on postural sway; and Webster et al. (1984) noted the effect of visual scanning training during navigation on wheelchair navigation. Such studies appear to indicate that ADLs must be specifically taught if the functional recovery of stroke patients is to be improved. The findings of studies on the effects of forced use in the treatment of hand dexterity and walking corroborate this finding. Applying a sling to the healthy arm (Constraint-Induced (CI) therapy; Taub et al., 1993) and walking on a treadmill during partial body weight bearing (Hesse et al., 1995) appear to positively influence the usage of the paretic arm in ADLs and independent walking, respectively.

CONSTRAINT-INDUCED (CI) MOVEMENT THERAPY OR 'FORCED' USE OF UPPER EXTREMITY FUNCTION:

Most studies published on the effects of CI therapy are case studies or pre-experiments (N=5; Blanton & Wolf, 1999; Kunkel et al, 1999; Liepert et al.,1998; Miltner et al., 1999; Sabari et al., 2001) or controlled trials lacking sufficient control for placebo-effects or intensity of treatment (N=3; Ostendorf & Wolf, 1981; Page et al., 2001; Taub et al., 1993). However, two recently published RCTs included an adequate control for attention and the amount of exercise; one study carried out in the chronic phase after stroke (van der Lee et al., 1999) and one in the acute phase (Dromerick et al., 2000).

In the Van der Lee study, stroke patients (N=66) were randomly allocated to either forced use therapy (immobilization of the unaffected arm combined with intensive training) or a reference therapy of equally intensive bimanual training, based on Neuro-Developmental Treatment, for a period of two weeks. Outcomes were evaluated in terms of ADL (Rehabilitation Activity Profile; Motor Activity Log (MAL) and Problem Score), dexterity (Action Research Arm (ARA) test), and neuromuscular impairments (Fugl-Meyer Assessment scale). One week after the last treatment session, a significant difference in efficacy in favor of the forced use group compared to the bimanual group was found for the MAL and ARA scores. The differential effect on the ARA score was not clinically relevant (MCID 5.7 pnts), but was still significant at follow-up. The differential effect on the MAL was clinically relevant (MCID 0.5 pnts), but was not observed during follow-up. The other outcome parameters revealed no significant differential effects. After estimating the minimal clinical important difference and controlling for patient characteristics, it was found that the differences in treatment effect for the ARA and MAL scores were only clinically relevant for the patients with sensory disorders and hemi-neglect, respectively. Both the experimental and the reference group revealed clinically relevant improvements on all outcome parameters compared to baseline assessments suggesting that the intensity of treatment in both conditions may have had a positive influence on functional outcome. One year follow-up effects were observed only for the ARA score. The importance of the latter findings is that patients who have had a stroke more than one year ago still benefit from stroke rehabilitation. Limited evidence is available in literature on the effects of stroke rehabilitation in the chronic phase after stroke. In addition, Van der Lee and her colleagues demonstrate that the effects of forced use of upper extremity function are dependent on the existence of sensory disorders and hemi-neglect. One explanation is that forced use treatment facilitates the awareness of sensory perception, which is claimed to be liable to treatment even in stroke patients. Currently, there is no knowledge base on the impact of patient characteristics on the effects of stroke rehabilitation.

The results reported by Dromerick et al. (2000) support the findings of Van der Lee et al. (1999). They provide evidence that forced use of upper extremity during the acute

improves the functional recovery of dexterity. No attempt was, however, made to relate the outcomes in dexterity and ADL to patient characteristics. Overall, the findings by Van der Lee et al. and Dromerick et al. indicate that a high intensity of upper extremity function improves the recovery of dexterity and ADL.

EFFECTS OF PARTIAL WEIGHT BEARING SUPPORT (PWBS) DURING GAIT TRAINING:

More than ten studies are published on the effects of PWBS during gait training in stroke patients, that is, four case studies (Danielson & Stibrant-Sunnerhagen, 2000; Hassid et al., 1997; Hesse et al., 1997; 2001) and six controlled trials (Hesse et al., 1994, 1995 & 1999; Laufer et al., 2001; Teixeira da Cunha Filho et al., 2002; Visintin et al., 1998; of which 4 RCTs). Visintin et al. (1998) investigated the effects of retraining gait in stroke patients (N=100) through body weight support and treadmill simulation in one hundred stroke patients, who were randomly distributed in an experimental therapy (patients were trained to walk with up to 40% of their body weight supported by a body weight support (BWS) system with overhead harness), and a reference therapy (patients were trained to walk bearing full weight on their lower extremities). After a six-week training period (four sessions per week) the BWS group showed a significantly better over-ground walking speed, over-ground walk endurance, functional balance and motor recovery compared to the reference group. Walking without BWS delayed the patient's ability to walk on a treadmill. The latter findings again suggest that an early start of intensive gait training facilitates the recovery of hemiplegic gait. These findings are supported by the results of several well-controlled trials on the effects of gait training with BWS (e.g., Hesse et al., 1994, 1995, 1997; see for overview Barbeau et al., 1998). In addition, a number of gait studies have shown that the training of treadmill walking (systematically manipulating speed) can improve walking speed and the coordination of walking (e.g., Kwakkel & Wagenaar, 2002; Sullivan et al., 2002; Wagenaar & Beek, 1992; Wagenaar & van Emmerik, 1994 & 1996).

CONCLUSIONS

Currently, the best evidence is that stroke patients will benefit from expert care on a stroke rehabilitation ward. An important aspect of expert care is the early start of intensive rehabilitation (physical therapy, occupational therapy and speech therapy). In addition, forced use of upper extremity function (or CI-therapy) in the chronic and acute phase after stroke improves dexterity, whereas partial body weight support during gait training facilitates walking ability. The evidence presented for the effectiveness of a two-week forced use program of upper extremity function (or CI therapy) in the chronic phase after stroke suggests that the dose-response relationship depends on sensory disorders and hemi-neglect. Intensity of treatment is apparently an important component of both CI-therapy and partial body weight support during gait training.

Future research should detail the dose-response relationship in terms of timing and duration of augmented exercise therapy. In addition, the influence of patient characteristics on the dose-response relationship should be investigated. For example, sensory disorders and hemi-neglect most likely have an important impact on the effects of stroke rehabilitation (e.g., CI-therapy, but also gait training). In addition, we have to focus on research that will provide us the theoretical understanding of the underlying mechanisms of functional limitations in, for example, locomotion, stair-climbing, grasping and dressing and the impact by exercise therapy (see Wagenaar & van Emmerik, 1994).

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UNDERSTANDING TONE AND SPASTICITY (S3)

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Upper Motor Neuron Syndrome (UMNS) can occur after the onset of stroke and is a term that may be used to describe clinical symptoms of alteration of movement. Although the clinical diagnosis is evident, individuals present with large variations in clinical signs of disturbed movement. For that reason, the term "spasticity" is used in clinical practice and in literature to describe different sets of symptoms.

A clear definition of altered muscle function in UMNS is needed to describe methods for measurement and treatment. In this article, a classification of symptoms of altered muscle function in UMNS will be presented. The terminology, used for the distinct symptoms is in fact arbitrary. Proper definition however is a prerequisite for unambiguous communication.

CLASSIFICATION OF IMPAIRMENT OF MUSCLE FUNCTION

In a patient with UMNS, two sets of symptoms can be distinguished: a) impairment of muscle activation; b) change of biomechanical properties of the muscle-tendon complex.

A. Impairment of muscle activation

Muscle activation concerns the "motor"- function of the muscle, and is related to EMG activity.

Impairment of muscle activation can be divided into two sets of symptoms: **deficit symptoms** and **excess symptoms**.

Deficit symptoms are caused by the reduction or loss of normal voluntary muscle function. In the case of mild involvement, only loss of dexterity of movement, diminished ability to perform fast alternating movements and enhanced fatigability are present (1). In more severe involvement, the patient can perform synergistic voluntary movements: the ability to move in a single joint is reduced or lost, voluntary movement is only possible in a partial or total pattern. The lowest level of motor control is voluntary movement in a general flexion (mostly present in the upper limb) or extension pattern (mostly present in the lower limb). Synergistic voluntary movements will also be described as "loss of selective motor control" (2).

Also, the level of muscle force is reduced. In the case of synergistic movement, the level of muscle force is dependent of the posture of the patient and the kind of movement: the force during movement within a pattern will be much higher than in a movement opposite to the pattern. For that reason, grading of muscle force is only reasonable when selective motor control is present.

In the past years there has been growing interest in the deficit symptoms of UMNS. There are specific motor tests for hemiplegia, based on rating the level of selective motor control (3;4). This approach is more suitable for describing of the deficit symptoms in a UMNS.

Today, they are considered to be the main factor of impairment of muscle function in UMNS (5-8). The presence of a paresis is due to a lesion of the fast-conducting part of the corticospinal system. The degree of paresis in an extremity is more pronounced distally than proximal (9). The term "Reduced Output Paresis" (ROP) can be used to describe this reduction of recruitment of the muscle (10).

Excess symptoms reflect the presence of abnormal muscle activity.

Clinically, the presence of abnormal muscle activity can either be noticed during passive joint movements, while the patient is in maximal relaxation, or observed while the patient is performing motor tasks.

Passive movement

During (very) slow passive movements, the muscle tone can be examined. Some patients show a raised muscle tone during a very slow passive stretch (hypertonia defined as a non-velocity-dependent resistance to passive stretch). This increased resistance could be due to a continuous activation of the stretched muscle, as a sign of a raised stretch reflex activity (tonic stretch reflex activity, TSR). EMG activity has to be present.

An operational definition of spasticity is described as : "a motor disorder characterised by a velocity-dependent increase in tonic stretch reflexes ('muscle tone') with exaggerated tendon jerks resulting from hyperexcitability of the stretch reflex as one component of the upper motor neuron (UMN) syndrome" (11).

In a clinical way, the presence of spasticity, defined as the velocity-dependent resistance to passive stretch, can be examined during fast passive movements. If only a catch (clasp-knife symptom) can be noticed, the spasticity is mild. In more severe spasticity, a clonus in the muscle can be evoked, or a the movement is blocked. The definition of spasticity is applied to this phenomenon (12). It is caused by increased dynamic stretch reflex (DSR) activity. A great deal of research has been carried out to determine the nature of the increased stretch reflex activity, as this was considered to be as the major impairment in UMNS. The increase in DSR can be caused either by a raised gain of the stretch reflex, or a lowered threshold of the reflex. The latter appeared to be the most important factor (13). The increase in stretch reflex activity is caused by a reduction in the inhibitory influence of the 1a afferents. This reduction is the result of disturbance of the spinal motor system. The presence of spasticity is dependent of the balance between the excitatory medial reticulospinal tract and the inhibitory lateral reticulospinal tract (14).

The distinction which was formerly made between gamma and alpha spasticity has been abandoned (15).

Hyperreflexia of tendon jerks, abnormal musculo-cutaneous reflexes (such as Babinski's response) and the presence of a

flexor reflex are also excess symptoms. The hyperreflexia of tendon jerks is associated with the increased excitability of the alpha motor neurones. The Babinski response is due to a lesion of the pyramidal tract. The response is considered to be a late flexion reflex, as are other abnormal cutaneous reflexes including the presence of a spinal stepping generator. Late-reflex pathways are closely linked with the presence of a flexor reflex and spontaneous spasms (as seen in Spinal Cord Injury). They may also be associated with the spinal stepping generator.

Involuntary activity related muscle activity

When performing tasks, three other features of involuntary muscle activation can be present:

- **mirror movements** can be present in hemiplegic patients: strong voluntary contraction of a muscle on the unaffected side evokes contractions in the same muscle on the hemiplegic side;
- **involuntary synergies** can arise during the performance of a motor task. For example: the occurrence of a flexor synergy in the arm of hemiplegic patients when walking. Mirror movements and involuntary synergies are associated reactions, due to a motor effort, and can be considered as “radiation” of activity (16)(20).
- **postural and activity dependent muscle activity.** Involuntary muscle activity can be present during the performance of a task. For example: the clawing of the toes when walking. The muscle contractions develop gradually during walking. These reflexes seem to be related to the presence of long-latency reflexes, as an expression of the enhanced influence of the vestibulo-spinal and reticulo-spinal system. The influence of emotional stress on the presence of involuntary muscle activation can be explained in the same way.

Voluntary movement

During voluntary movement, co-contraction of the antagonist is also an excess symptom. Clinically, co-contraction can sometimes be observed as a paradoxical movement. For instance, the patient is asked to extend the elbow, but a flexion movement takes place: the co-contraction of the flexors is more powerful than the contraction of the extensors of the elbow. The presence of co-contraction is a component of normal reciprocal innervation (17). There is no relationship between the presence of co-contraction during voluntary movement and spasticity during passive movement (18).

Stretch reflex activity can also be present during voluntary movements. If EMG activity is permanently present during movement, it can be defined as Tonic Stretch Reflex activity. Both co-contraction and Tonic Stretch Reflex activity can counteract the agonist of movement. This can be described as “Subtraction Paresis”.

Terms as described in this chapter, are used in different ways.

Spasticity has been used for all signs of a UMNS (all changes in muscle activation and biomechanical

changes), or for all signs of abnormal muscle activity, the excess symptoms. As some therapeutic interventions (as spasmolytic drugs as baclofen and tizanidine) only have effects on the stretch reflex, the distinction between the different excess symptoms as presented is useful in clinical practice.

Muscle tone is also used on different ways. In physiotherapeutic treatment methods, muscle tone is not only used estimating the degree of resistance in passive joint movement, but also for abnormal muscle activity during active movement (such as the involuntary synergistic movements and abnormal postural dependent muscle activity). It is proposed to use the term muscle tone only for the examination of the resistance in a muscle during passive joint movement.

Involuntary activity related muscle activity is also described as associated reactions. However, mirror movements, involuntary synergies and posture and activity related abnormal muscle activity seem to have different pathological backgrounds. For that reason, a different response to therapy can be expected.

B. change of biomechanical properties of the muscle-tendon complex

Clinically, increased muscle stiffness (defined as hypertonia: non-velocity dependent resistance to passive joint movement) can be observed during slow passive stretch of a muscle after maximal relaxation. It is important to choose a posture for the patient, in which maximal relaxation can be achieved (i.e., lying supine, flexion-abduction-external rotation in the hip and flexion in the knee will relax the Triceps Surae Muscle). Hypertonia can be caused by continuous activation of a muscle, in which case it is classified as an excess symptom (Tonic Stretch Reflex activity: see above). Without EMG activity, hypertonia can be caused by changes in the biomechanical properties of the muscle (19). Other causes, such as secondary joint changes, heterotopic ossification etc, must be excluded. The increased stiffness can be caused by a change in the connective tissue (muscle shortening), but also by a change in stiffness within the muscle itself (20;21). Increase of collagen-1 in muscles of patients with a UMNS has been demonstrated, corresponding with the Ashworth tone score (22). Also, an initial raise of resistance on passive stretch has been described, diminishing after repeated passive stretch, known as thixotropy. Thixotropy could be attributed to abnormal cross-bridging of the muscle filaments (23-26).

The development of muscle shortening is a well known phenomenon in clinical practice. Nevertheless, this aspect of change in muscle function in UMNS has received little attention in research. Muscle shortening takes place in the muscle belly (27). In neurological studies, muscle shortening is an “forgotten” subject, and only in France has research been carried out on this subject (28). It is unclear why muscle shortening is present in some patients, and not in others. The time-course of the occurrence of muscle shortening after the onset of UMNS is also unknown.

The classification of impairment of muscle function in UMNS is summarized in Table 1.

CONCLUSION

In conclusion, the changes in muscle function in UMNS are very complex. Differentiation between the several kinds of disturbance in muscle function is important. Only by proper definition of the different clinical symptoms, communication about results of treatment procedures is possible.

At present time, no generally accepted classification and definitions is available. A clearly defined classification of signs of altered muscle function has been proposed.

IMPAIRMENT OF MUSCLE ACTIVATION		
DEFICIT SYMPTOMS	EXCESS SYMPTOMS	CHANGE OF BIOMECHANICAL PROPERTIES OF THE MUSCLE-TENDON COMPLEX
- paresis: Reduced Output Paresis	- passive movement - spasticity (DSR) - hypertonia (TSR)	hypertonia
- loss of selectivity of movement - voluntary synergies - dependency on posture	- active movement - co-contraction (DSR) - TSR : subtraction paresis - postural and activity dependent muscle activity - mirror movements - involuntary synergies	thixotropy
- loss of dexterity of movement	- abnormal responses - flexion reflex - abnormal musculocutaneous reflexes	muscle shortening
- enhanced fatiguability		

DSR = Dynamic Stretch Reflex; TSR = Tonic Stretch Reflex

Table 1. Summary of impairments of muscle function in Upper Motor Neuron Syndrome

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BIOMECHANICS OF LOWER LIMB FUNCTION AND GAIT (S4)

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"Walking is simple to do but surprisingly difficult to understand scientifically."

—Gottschall and Kram (1)

INTRODUCTION

Normal human walking is characterized by smooth, rhythmic patterns of motion, and requires relatively little effort by the ambulator. For able-bodied individuals, walking on level, well-lighted surfaces generally proceeds with little, if any, mental burden, allowing control of the activity to be relegated to an almost subconscious level. While apparently a learned behavior, it is remarkable that everyone seems to arrive at the same general solution for ambulation. It is believed that able-bodied ambulators have similar walking characteristics because they inherently seek the most energy-efficient means of locomotion.

Many conventional ideas about normal human walking originate from concepts first presented in a landmark paper entitled, "The Major Determinants of Normal and Pathological Gait" (2). In this paper, the authors identified six "determinants" of normal gait that were claimed to minimize the displacement of the body's center of mass and smooth its trajectory, resulting in reduced energy expenditure. Unfortunately, no empirical data supporting the theory were presented in the original paper. Nevertheless, the concept of the six determinants of gait is pervasive in the clinical and research fields involved with gait. The determinants are routinely taught to prosthetists and orthotists, physical therapists, medical students, kinesiologists, and other persons involved in the analysis and study of human walking. In light of new information and increased understanding about normal ambulation (3-6), many people are now becoming convinced that the original six determinants of gait, while important attributes of normal walking, probably serve functions other than those originally claimed. During the latter half of the 20th century, instrumented gait analysis has furthered our understanding about gait. Nonetheless, many questions remain to be answered about normal walking, and what interventions are required to

best improve pathological gaits. Quantitative gait analysis has been used to objectively describe the characteristics of persons who walk with lower limb orthoses or prostheses, which has proven to be useful for quantifying gait modifications and for determining limitations in orthotic or prosthetic performance that prevent persons with gait pathologies from walking more normally. These measurements can assist in the identification of specific problems that are typically encountered by persons who walk with orthoses or prostheses. Edelman (7) observed that augmenting the human body with a prosthesis or orthosis markedly affects the individual's mode of travel, and that the task of the clinician should be to recognize optimal gait with a given device so that departures from the standard can be identified, their causes determined, and, wherever possible, corrected. She further stated that of all the elements affecting locomotion, those most amenable to change relate to the device; thus, in the description of walking patterns, emphasis should be placed on device design, alignment, and fit.

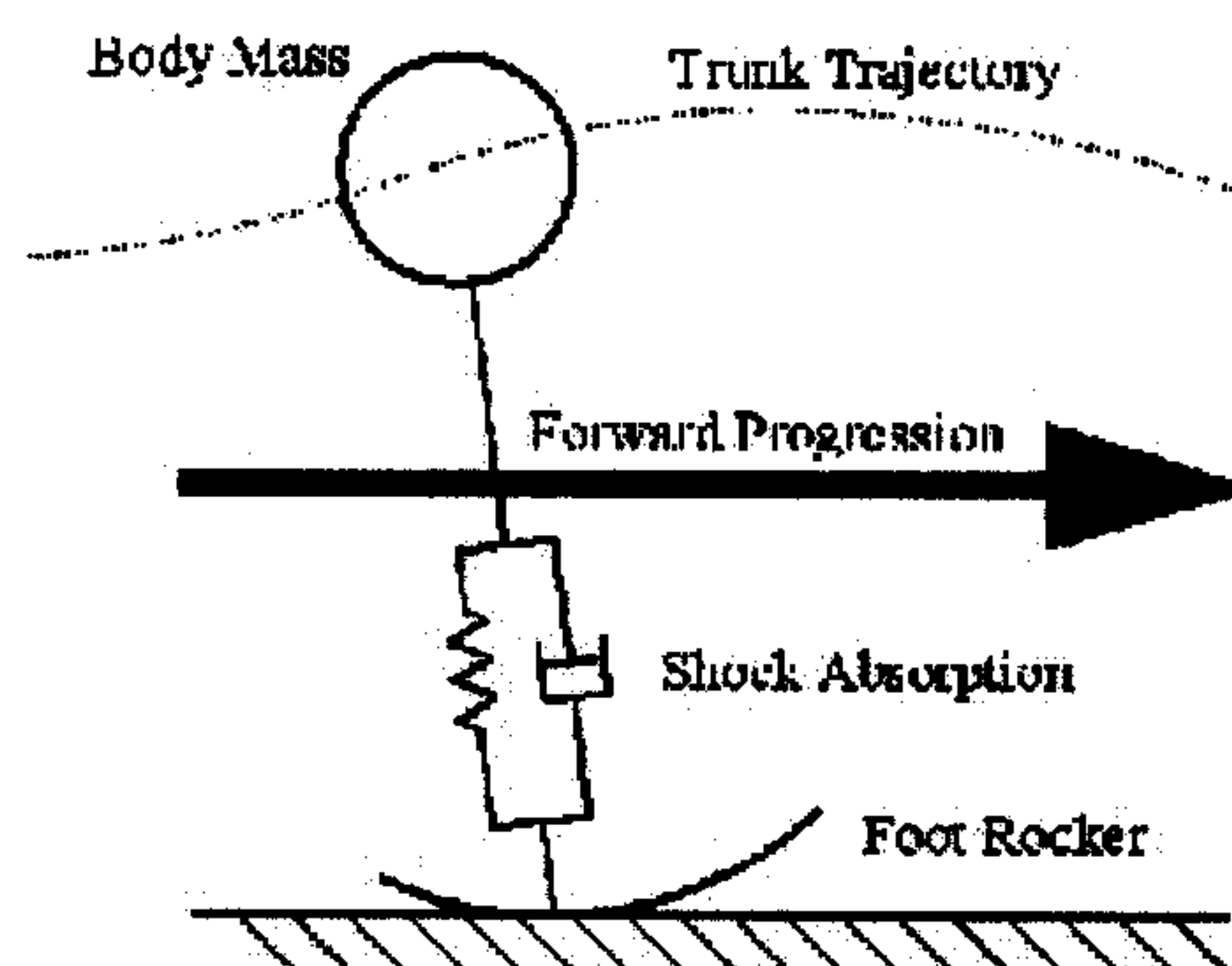


Figure 1. Conceptual walking model that incorporates various aspects of the NUPRL and RERP research effort.

Our research laboratory, the Northwestern University Prosthetics Research Laboratory (NUPRL) and Rehabilitation Engineering Research Program (RERP), has developed a conceptual model of walking that incorporates many of the functional elements required for a normal gait (Figure 1). We are focusing our research efforts on foot roll-over shape (i.e., foot rocker), shock absorption, gait initiation and termination, balance and posture, energy efficient mechanisms for achieving and maintaining forward progression, and the trajectories of the segmental and whole-body centers of mass. Our goal is to improve current orthotic and prosthetic technologies to enable persons with disability to walk with increased efficiency. To do this, we need an increased understanding of the functional aspects of walking. Important functions associated with walking include:

1. Gait Initiation and Termination
2. Balance and Upright Posture
3. Stability of the Stance Leg

4. Execution of the Stepping Motion
5. Forward Progression/Propulsion
6. Shock Absorption
7. Energy Conservation

This essay will describe and examine these functions as they occur in normal ambulation, and explore how compensations and modifications to gait result in persons who have sustained a stroke. Many of the ideas presented here are preliminary in nature and have not been thoroughly investigated, yet they represent the assessment of collective experience and knowledge in human gait analysis.

GAIT INITIATION AND TERMINATION

Walking requires that a person be able to successfully accelerate the body forward from a standing position, and be able to terminate the activity while maintaining an upright, balanced state. During quiet standing, the body possesses significant gravitational potential energy but very little kinetic energy. To initiate walking, it appears that able-bodied individuals utilize actions that exploit their store of gravitational potential energy. The person makes the system statically unstable by dorsiflexing their ankles or leaning their trunk forward, letting gravity pull them over. Technically, the person is falling. Carlsöö (8) stated that, "...walking is initiated by the body losing its balance as a result of the cessation of activity in certain postural muscles." Falling forward initiates a process in which forward velocity increases, decreasing gravitational potential energy while simultaneously increasing their kinetic energy, a transformation of energy. Some intervention is required, within a short window of time, if the person is to maintain upright stability. For walking, the intervention that occurs is the stepping action of one leg to a position in front of the body. Mann et al. (9) suggested that gait is initiated by the body becoming unbalanced in a controlled manner, permitting a person to pick one foot up off the ground in order to take the first step. During the first step, energy is primarily supplied by the hip flexors to lift the leg and step forward. The ankle plantarflexors don't contribute much during the first step, but tend to be more active during the second step (10). The forward kinetic energy that is generated by the falling body aids in the transfer of body weight from the trailing to the leading leg, thereby restoring the gravitational potential energy that was used for gait initiation. Steady-state walking speed is typically achieved in 2-3 steps.

Less is known about gait initiation in persons with gait pathologies. Hesse et al. (11) studied the symmetry of gait initiation in able-bodied and hemiparetic subjects. When the hemiparetic subjects initiated gait with their affected leg, the center of pressure pattern was similar to that of the able-bodied subjects. However, when they initiated gait with their sound leg, the swing period and step length were shorter and the center of pressure showed a more significant medial-lateral sway with no corresponding movement of the body center of mass.

Gait termination—the dynamic transition from steady-state walking to a quiet standing posture (10)—has been investigated to a lesser degree than initiation. It is, in many respects, a mirror-image of gait initiation. Hase and Stein (12) identified three different mechanisms used to terminate gait: 1) braking mechanism in the forward leg; 2) inhibition of push-off phase of the stance leg; and 3) if the previous two mechanisms were not sufficient, the subjects rose up on their toes in order to convert remaining kinetic energy into potential energy and thus stop forward progression. In a study of young and elderly able-bodied subjects, and elderly subjects with type II diabetes affected by peripheral neuropathy, Meier (13) observed that the diabetic subjects took the longest relative time to develop maximum braking forces compared to the young and elderly subjects. Whittle (14) pointed out that because of the demand to arrest forward momentum of the body, gait termination appears to present a greater challenge to the neural control system, which is particularly challenged in stroke.

BALANCE AND UPRIGHT POSTURE

Body mass distribution is such that approximately two-thirds of its mass is carried above the hip joints when the body is in a standing position. Being top-heavy as we are, stability is challenged and active intervention is required to maintain balance of the head, arms and trunk (HAT) over the legs and pelvis. Abdominal and pelvic muscular effort is reduced by holding the trunk in a vertical orientation and positioned over the legs. Able-bodied individuals tend not to notice significant muscular demand to maintain upright posture, though perceived effort increases considerably as we lean our trunks from a vertical position.

Perry (15) suggested that the walking human might be functionally subdivided into a passenger unit (HAT and pelvis) and a locomotor unit (pelvis and legs). During walking, the locomotor unit is responsible for transporting the body from one place to another. The passenger unit doesn't actively contribute to the walking process, but it must balance itself over the locomotor unit, a major determinant of muscle action within the locomotor system.

During standing, *static balance* is achieved by positioning the body's center of gravity vector (weight line) within the perimeter of the base of support created by the feet. If the center of gravity were to move outside the base of support, the person would fall over. In theory, quiet standing balance can be attained without any muscle action if the center of mass of the passenger unit is exactly aligned over the axes of rotation of the joints of the locomotor unit (15). However, the slightest sway would unbalance every segment. Quiet standing is characterized by small, but continuous, motions of the body's center of gravity. The center of pressure under the feet, a point force representing the net effect of the distributed force between the body and the ground, is used to manipulate the position of the center of gravity and rein it within the base of support. Winter (16) suggested that standing balance is achieved through a combination of hip and ankle joint control strategies. Motion about the ankle joints is used to control whole body inclination, while hip motion is used for controlling upright posture of the HAT.

Bipedal gait provides a particularly challenging balance task to the central nervous system that is grossly different than the balance task during standing (17). During walking, the ambulator must maintain a *dynamic equilibrium* in which the motion of the body mass plays a role in maintaining an upright posture and balanced state. The dynamics associated with the forward momentum of the moving body of an able-bodied person enables body configurations to be assumed during gait for which static balance wouldn't be possible. The center of gravity doesn't need to be positioned directly over the base of support during gait, and can actually be used to facilitate walking. For example, in single support the medial proximity of the center of gravity relative to the base of support facilitates lateral motion towards the contralateral side of the body in preparation for initial contact of the swing leg. As in standing, the center of pressure under the feet appears to be used to effectively control the center of gravity in order to maintain dynamic balance. Many persons with stroke gait utilize slow, labored motions that are not very dynamic and result in low walking speeds, which prevent them from being able to take advantage of the forward momentum and energy transfers that characterize able-bodied gait.

Stroke patients have an increased risk of falling during ambulation (18). Perry (19) suggested that hemiplegic patients sometimes fall when they fail to align themselves over the leg on their affected side because they do not sense the need to adapt their weight distribution and fail to shift their trunk appropriately during gait. Their sense of lateral balance, including awareness of the weight of the unsupported side, is compromised as a result. Hyndman et al. (20) reported that loss of balance, misjudgment, foot dragging while walking, turning, and rising from sitting to standing were most frequently described as activities leading to falls.

STABILITY OF THE STANCE LEG

The stance leg must have the ability to support the weight of the body during standing and walking, especially during the time of single support when the body progresses forward over the supporting leg while the contralateral leg is off the ground and swinging forward. This requires a combination of adequate muscular strength and appropriate leg positioning. The body appears to increase stability at the lower limb joints through careful control of the ground reaction force (GRF) vector during walking, acting and reacting in order to reduce joint moments and muscle forces.

The GRF vector passes relatively close to, or through, the axes of rotation of the hip, knee, and ankle joints during much of the stance phase (15). This creates shorter lever arms at the joints, reducing the moments about the joints that are required to maintain stability and facilitate forward progression. During stance phase, the muscles about the hip joint are required to maintain an upright posture of the HAT, and the muscles about the ankle joint are important for creating a functional roll-over shape. Stability of the knee joint is crucial during weight bearing to prevent the leg from collapsing under the body. Knee extension can be maintained during standing and much of the stance phase

of gait with reduced muscular effort by orienting the GRF vector so that it passes through or close to the knee joint's axis of rotation, which reduces the moment produced about the knee and lessens the demand for muscle activation. When the GRF vector is directed anterior to the knee axis, knee extension is maintained by the ligamentous structure surrounding the knee so muscles are largely silent.

Weight transfer onto the accepting limb during gait is rapid and fairly abrupt, which creates the challenge of accepting rapidly moving body weight in a manner that both absorbs the shock of floor contact and creates a stable limb over which the body can advance (15). Normal ambulation is characterized by a stance-phase knee flexion wave during the loading response phase, which serves to provide shock absorption by decreasing the leg stiffness (4). The knee is driven into stance-phase flexion because the GRF vector is oriented posterior to the knee's axis of rotation, thereby challenging stability that necessitates eccentric contraction of the knee extensors. If stance-phase knee flexion is to occur during gait, sufficient muscular strength of the knee extensors will be required to recover from the flexed position, though some degree of knee extension may be restored passively through elastic mechanisms (i.e., tendons). Persons with insufficient knee extensor strength may walk in such a way that stance-phase knee flexion is considerably reduced or eliminated. For example, stroke patients sometimes lean forward during gait to orient the GRF vector anterior to the knee axis, reducing the potential for buckling. However, eliminating or reducing stance-phase knee flexion increases shock to the system, which may be compensated for by a reduction in walking speed.

EXECUTION OF THE STEPPING MOTION

Ambulation requires that the person have the capability to advance the leg from behind to in front of the body to execute the stepping motion in a smooth, efficient manner that does not disrupt forward progression. To accomplish this objective, the leg must be shortened sufficiently so that it does not contact the ground during swing, and it must be rapidly lengthened as it moves anterior to the body in preparation for initial contact and stance phase. Walking is a dynamic process, requiring the ambulator to flex and extend his legs at a sufficiently high rate in order to capitalize on the momentums associated with the moving body masses and to take advantage of energy saving mechanisms involving mechanical energy transformations.

Temporal parameters of walking are also of major concern. Able-bodied ambulation is characterized by left-right symmetry. Generally, the stance and swing phases for one leg are nearly equal in duration to those of the other, providing an even, rhythmic pattern during gait. The stance phase duration during freely-selected able-bodied gait is generally about 62% of the gait cycle, with swing phase comprising about 38%, and each double-support phase lasting approximately 12%. These phase durations are modified with faster or slower walking speeds (21). Cadence, the stepping rate, appears to be influenced significantly by the swing leg, as evidenced by the effect of knee damping mechanisms in transfemoral amputee gait (22). Without

the ability to control the swing phase duration of the leg, walking speed is difficult to change.

Walking speed is often used as an overall indicator of the quality of gait. Able-bodied adults generally adopt a freely-selected walking speed of about 1.3-1.4 m/sec, and are able to comfortably walk across the range of speeds from about 0.8-1.8 m/sec (23). Persons with gait pathologies typically walk at slower speeds (24-26), and the range of speeds at which they are able to walk tends to be narrower than that of able-bodied persons (27). Walking speed is determined by both step length and cadence. As the limb prepares for initial contact, the swing leg hip should be appropriately flexed and the knee extended to move the foot to a position in front of the body and allow for an adequate step length. The inability to flex the hip or extend the knee sufficiently will result in short step lengths, slowing forward progression. Faster walking speeds tend to be accompanied by greater pelvic rotation (28), which serves to further increase the step length. The rate of stepping relies on the ability to transfer body weight to the leading leg and swing the trailing leg forward without hindering forward progression. Otherwise, forward kinetic energy of the body drops precipitously during double support phase and diminishes the efficiency of mechanical energy exchange, requiring additional metabolic energy to be generated to restore the body's gravitational potential energy.

Knee flexion is the primary mechanism by which the leg is effectively shortened for swing phase foot clearance. Many people mistakenly assume that any amount of knee flexion serves to shorten the leg, and that even a small quantity is better than none at all. This is not true. Using a simple model of the leg with the ankle joint held neutral, we determined that during the first 20° of knee flexion the hip-toe distance lengthens by about 2% (29). Further flexion of the knee beyond 20° begins decreasing the hip-toe distance, and at about 40° this distance is equivalent to that when the knee is fully extended. The hip-toe distance doesn't shorten beyond that of the fully-extended leg until the knee flexion angle exceeds 40°. The implications for this are that persons with gait pathologies are actually hindered during swing phase if they cannot achieve at least 40° of knee flexion, and that many persons would probably be much better off walking with their knee locked in extension. The problem of swing leg foot clearance is compounded in stroke patients when insufficient knee flexion during swing is accompanied by excessive ankle plantarflexion, which serves to further increase the hip-toe distance.

Knee flexion during swing phase converts the leg into a compound pendulum, enabling the leg to swing forward with less effort. The leg's moment of inertia—a parameter proportional to the effort required to rotate a body with distributed mass—is reduced as the knee is flexed and the foot and shank masses are brought closer to the hip joint's axis of rotation. This reduces the natural period of the leg, enabling the leg to swing forward in shorter time than if the leg were fully extended (30). Additionally, the smaller moment of inertia reduces the effort, and thus the energy, required to swing the leg forward. Persons who have sustained a stroke may walk with an extended knee on the

affected side, which may cause a relatively longer swing phase (and thus a shorter stance phase) on the affected side compared with their sound side (31). The shorter stance phase on the affected side has often been attributed to their lack of security on the affected limb, but it could simply result from the pathomechanics that increase the relative time required to swing the affected limb forward during gait.

Persons with gait pathologies that affect the knee and ankle joints are often observed to lift the hip on the side of the affected leg in late stance to begin accelerating the leg for swing phase. This compensatory action is often referred to as 'hip-hiking', a mechanism that is typically attributed to the need for increased swing phase toe clearance. However, this motion may also help initiate knee flexion in late stance, or it may be used to accommodate the effective leg lengthening that occurs during the first 20° of knee flexion (32). Other compensatory actions that are routinely employed for swing leg foot clearance are vaulting and circumduction. These compensatory actions are metabolically expensive, undoubtedly increasing the energy expenditure required to walk.

FORWARD PROGRESSION/PROPULSION

The basic objective of the locomotor system is to move the body from one place to another, and humans apparently try to expend minimal metabolic energy in doing so. We appear to utilize mechanisms that conserve mechanical energy and preserve forward momentum of the body, enabling forward progression with only relatively small additions of metabolic energy from step to step. Exactly how and when muscles add energy during the gait cycle has not yet been resolved.

Perry (15) suggested that three foot rocker mechanisms—heel, ankle, and forefoot—serve to facilitate forward progression. We believe that these three foot rocker mechanisms are integrated during walking to create a single, smooth 'roll-over shape' that facilitates progression of the center of pressure (COP) distally along the planter surface of the foot, which effectively lengthens the leg and flattens the trajectory of the body center of mass (BCOM) (33). The flatter trajectory of the BCOM reduces the accelerations imposed on the body during gait, making walking less abrupt and more comfortable for the ambulator. Our laboratory has shown that the physiologic foot-ankle roll-over shape is relatively invariant to changes in walking speed, heel height, added weight, and sloped surfaces (34). Some pathologies, such as stroke, may cause an initial contact on the forefoot instead of the heel due to an equinus posturing of the foot, which alters the roll-over shape of the foot-ankle mechanism and adversely affects forward progression of the body. Furthermore, the altered foot rocker mechanism disrupts forward momentum of the body as a whole and decreases walking speed (35). The creation of prosthetic and orthotic devices that can automatically adapt to changing walking conditions and provide appropriate roll-over shapes is of continued research interest.

There are two double support phases in each gait cycle, and the duration of each is approximately 12% of the gait cycle

at freely-selected walking speed. During double support, body weight is rapidly transferred to the leading leg so the trailing leg can be lifted and advanced in front of the body. Weight transfer must occur quickly and efficiently so the knee of the trailing leg can begin flexing in preparation for swing phase and the leg can begin accelerating forward. Knee flexion and ankle plantarflexion in the trailing leg during the double support phase serve to lengthen the leg, allowing it to maintain contact with the ground and provide stability to the body while facilitating transfer of load to the leading leg. The pelvis, serving as a mobile link between the two legs, facilitates smooth transmission of body weight from one leg to the other and provides shock absorption during the process (3). Rapid flexion of the hip in late stance accelerates the leg forward, and further knee flexion occurs passively. Inhibition of knee flexion at the end of stance phase, or delay in its initiation, will prohibit or reduce acceleration of the trailing leg, prolonging the double support phase and slowing progression of the body. This could contribute to the longer stance phase duration that is typically observed on the sound side of persons with unilateral gait pathologies, as in stroke where extensor synergy of the lower limb is often observed.

Metabolic energy must be generated by muscles from one step to the next in order for walking to proceed. Generating horizontal propulsive forces have been estimated to be about one-half of the net metabolic cost of normal walking (1). How this energy is generated and when it is added during the gait cycle is still not well understood. The ankle joint has been the focus of many of the research investigations involving propulsion during gait. Winter et al. (36, 37) claimed that ankle 'push-off' serves to propel the body forward and is the primary means for adding required energy for walking, accounting for about two-thirds of new energy generated during gait. However, the notion of 'push-off' by the ankle plantarflexors remains controversial. Perry (15) favored the term 'roll-off', a passive process involving the body moving forward over the forefoot rocker, instead of 'push-off'. Sutherland et al. (38) suggested that the ankle plantarflexors don't propel the body forward, but they do provide an essential stabilizing effect in late stance that makes it possible to obtain maximum step length. Meinders et al. (38) reported that ankle plantarflexor work is primarily used to increase the leg energy and accelerate the leg into swing, and that most of this energy is recovered by transfer to the trunk when the swinging leg is decelerated at the end of swing phase and it therefore contributes to maintaining the forward velocity of the trunk. During stance the plantarflexors are active to stabilize the ankle and reduce passive dorsiflexion. By doing so, they may facilitate anterior progression of the center of pressure under the foot and contribute to the formation of a functional roll-over shape. While they probably don't inhibit forward progression of the body by decreasing forward velocity or restraining forward momentum, as some investigators have claimed (38, 40), the plantarflexors probably aid in the transformation of kinetic energy to gravitational potential energy by reducing ankle dorsiflexion and allowing the body to roll forward on the

foot rocker towards its summit in mid-stance.

Some researchers have ignored the importance of the hip musculature to forward progression during gait, possibly because the dynamic models that are used to analyze joint moments and powers are especially limited at the hip. EMG data suggests that hip extension may be utilized at the beginning of stance phase to pull the body forward while providing lift to restore gravitational potential energy. In late stance and in early swing, energy from hip flexion appears to create a 'pull-off' burst to accelerate the swing leg forward. Riley et al. (41) suggested that propulsive adaptations to changing walking speed occur primarily at the hip and secondarily at the ankle. They reported that hip muscles, particularly the hip extensors, are critical to propulsion. Furthermore, they stated that ankle function is primarily for support, but it is important to propulsion, especially at slow speeds. Dillingham et al. (42) reported that energy transfer associated with the deceleration of the swing leg by the hip extensors is a major contributor to the forward propulsion of the body.

SHOCK ABSORPTION

Shock absorption to reduce floor impact forces at the time of initial contact has been identified as one of the primary locomotor functions during normal walking (15, 17). Cushioning of impact forces generated during normal locomotion is achieved through the physical properties of biological tissues, footwear and surfaces (43), and through actions of the lower limb and pelvis such as stance-phase knee flexion and pelvic obliquity (3, 4, 15, 44). The motions that occur during the period of weight acceptance in normal walking provide a system to facilitate shock absorption. At heel contact in normal walking, ankle plantarflexion and knee flexion both serve as shock absorbers to lessen the impact of floor contact (15, 19, 45, 46), and hip flexion probably contributes to this action as well. Pelvic obliquity has also been identified as playing a role in reducing shock during gait (15, 44). Researchers have found that increasing knee flexion decreases the stiffness of the leg and diminishes transmission of mechanical shock from the foot to the skull (47-49). Winter and Sienko (50) showed that the knee absorbs considerably more energy during weight acceptance than either the hip or the ankle, leading some researchers to speculate that the knee is the major lower extremity joint for shock absorption (51).

The body appears to guard the head against potentially harmful impact shock (51-54), utilizing strategies that incorporate slower walking velocities, softer impact surfaces through footwear or flooring designs, and gait patterns with increased knee flexion at ground contact (47, 54). Bowker and Hall (55) and Bowker (56) stated that the absorption of shock by deceleration of a moving limb segment through eccentric contraction is possibly the major function of the great bulk of muscles in the lower limb.

Mechanisms of shock absorption involving the legs and pelvis are often disrupted in stroke patients due to gait modifications such as equinus positioning of the foot and extensor synergy of the leg. Cappozzo (57) found that a transfemoral amputee walking at his maximal speed

(about 1.5 m/sec) exhibited a vertical acceleration similar to that of normal subjects at their maximal walking speeds (about 2.4 m/sec), and suggested that the vertical acceleration—and the mechanical load associated with it—may be one of the limits to walking speed, both in normal and pathological gaits. Reduction in walking speed is a common gait characteristic in persons with stroke, and their attempting to reduce impact forces and vertical accelerations of the body may be part of the explanation for why this occurs. While many current AFO designs are intended to assist or improve the stepping motion by controlling plantarflexion during swing phase, this often occurs at the expense of compromising shock absorption at the ankle and modifying the rockers of the foot.

An individual's perception of leg compliance may be one of comfort (physical, psychological, or some combination thereof), increased stability during standing and walking, decreased force transmission from the ground, springiness with associated energy storage/release, and/or a sense of decreased stiffness in the walking surface. A better understanding of dynamic leg compliance will ultimately lead to more innovative shock-absorbing mechanisms that are designed to meet specific performance criteria for the function of a prosthesis or orthosis during ambulation.

ENERGY CONSERVATION

Able-bodied walking is characterized by remarkable efficiency. Humans appear to accomplish this by two primary means: managing the ground reaction forces in such a manner that the muscle moments about joints are reduced, and by conserving mechanical energy associated with moving the segmental masses of the body. Able-bodied ambulators are able to capitalize on these energy conserving mechanisms, reducing the amount of metabolic energy that must be added from step to step. One of the reasons why persons with gait pathologies may have increased energy expenditure as they walk is because these mechanisms may be adversely affected by their pathologic conditions, thereby reducing walking efficiency.

We now know that the vertical excursion of the body is not affected by pelvic obliquity or stance-phase knee flexion, two of the six determinants of gait (3, 4). Minimizing the vertical excursion of the body does not appear to be a fundamental goal that is utilized by the body to reduce energy expenditure, though excessive vertical excursion is probably wasteful of energy. However, the vertical excursion of the BCOM does appear to be reduced by the foot rocker mechanism, which serves to effectively lengthen the leg. Using a rocker-based inverted pendulum model, we have shown that the vertical displacement of the body can be completely accounted for by the geometrical constraints imposed by the legs and the roll-over shape of the foot (33). It has been suggested that because transfemoral amputees generally walk without stance-phase knee flexion on their prosthetic side, they will have a greater vertical excursion of their BCOM during gait with a concomitant increase in their energy expenditure. However, Gitter et al. (58) reported that even though energy expenditure was found to be increased in their transfemoral amputee subjects, the

magnitude of the vertical oscillations of trunks were not significantly different from those measured in able-bodied subjects.

Body mechanics appear to reduce the intensity and duration of muscular action involved in walking in order to minimize metabolic energy demand. As already mentioned, alignment of the GRF vector through or close to the hip, knee, and ankle joints reduces moment lever arms, enabling muscles to produce smaller forces and ultimately reducing metabolic energy demand. This observation is supported by the fact that electromyographic (EMG) recordings show that for much of stance phase the muscles are largely silent, indicating that little effort is required to maintain stability and advance the body forward (15). Muscles appear to be used primarily to accelerate and decelerate the HAT and the limb segments, with significant reliance on the momentum of the body masses that enable muscles to be turned off in mid-stance and mid-swing. Perry (15) suggests that sufficient gait velocity is required to preserve the advantages of momentum, thereby reducing the demand on muscles. Some investigators have claimed that forward fall of the body is the primary force propelling the body forward during steady-state walking, but this ignores the principle of conservation of energy. During steady-state walking, the energy of position (gravitational potential energy) is exchanged with the energy of motion (kinetic energy), and vice versa, decreasing the amount of metabolic energy that must be added to the system in order to walk (59). The trunk is at its peak elevation in mid-stance, coincident with its minimum forward velocity. As the body progresses forward and begins to fall from its summit, it loses gravitational potential energy and gains kinetic energy. The body's kinetic energy is greatest during the middle of double support phase when its forward velocity is highest and its elevation is lowest. The kinetic energy is used to drive the body forwards and upwards over the stance leg, restoring the body to its peak vertical position in mid-stance, a process involving a transformation of the kinetic energy to gravitational potential energy. This energy exchange is readily apparent when the mechanical energy of the HAT is calculated and graphed over the gait cycle. The gravitational potential energy and kinetic energy of the trunk are approximately 180° out of phase with each other and their peak-to-peak amplitudes are nearly equal, so that the summed energy of the HAT is nearly constant. Inman (59, 60) pointed out that the HAT is more or less carried as a flywheel during walking, allowing energy to be converted back and forth and thus minimizing the work required of the musculature. This observation suggests that the body is able to capitalize on this mechanical energy transformation and reduce the metabolic energy that must be added to in order to maintain steady-state gait. However, metabolic energy is required to set the appropriate initial conditions from step-to-step for this energy exchange to occur. Winter et al. (61) estimated the efficiency of this mechanical energy transformation to be nearly 50%. Furthermore, they suggested that similar mechanical energy transfers occur between adjacent limb segments to conserve mechanical energy. This transfer is a passive process that does not require muscle activity. The

mechanism for this form of energy conservation involves translational and rotational momentum transfers associated with limb dynamics during walking. Pathological conditions that reduce the ability of the body to conserve mechanical energy during gait through these transformations will undoubtedly increase the metabolic demand. Persons who have sustained a stroke have been shown to have very little if any mechanical energy exchange during walking, attributable primarily to a combination of their slow walking speeds and the compensatory actions they adopt (62).

The metabolic cost of walking has been shown to increase with more proximal levels of involvement in the leg. Able-bodied individuals appear to be able to walk efficiently across a relatively wide range of speeds from about 0.8-1.8 m/sec without a significant change in energy cost (23). Able-bodied subjects walking with immobilized ankle, knee, or hip joints have significantly higher energy costs (63, 64) and lower walking speeds (64) than normal. Ralston (63) reported that able-bodied subjects with one ankle immobilized had an increase in energy expenditure of 6%, and with one knee immobilized had an increase of 13%. In a similar study of able-bodied ambulators, Mattson and Bronstrom (64) reported an increase in energy cost of 10% when subjects walked with an unstable ankle, and an increase of 23% when walking with an immobilized knee. Waters et al. (65) have shown that energy expenditure increases with higher levels of lower limb amputation, and that amputees will lower their walking speeds to keep relative energy costs within normal limits. Stroke patients may reduce their walking speeds for similar reasons. Fish and Kosta (35) suggested the following factors contribute to increased energy cost in persons with stroke: neurologic involvement that affects proprioception and cognition; skeletal joint deformity; ligamentous laxity; and contractures.

CONCLUSIONS

We believe that the functional requirements of walking include: gait initiation and termination, balance and upright posture, stance phase stability, shock absorption, execution of the stepping motion, forward progression/propulsion, and energy conservation. Persons with pathologies adapt their gaits so that these requirements are optimized, but a modification to one of these requirements often deleteriously affects the others, so gait performance suffers. Efforts to improve orthotic or prosthetic devices should focus on increasing functionality of the device design. Seliktar (66) suggested that "...*orienting design effort initially towards function can produce, by relatively simple means, improvements in the locomotive characteristics of patients in a dynamic sense...*" Indeed, one of the fundamental rules of design is "form follows function." The key is to accurately determine what functions can be efficiently restored through improved orthotic design.

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APPLYING THE COCHRANE METHODOLOGY, TO A SYSTEMATIC REVIEW OF THE USE OF ORTHOTICS IN STROKE (S6)

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INTRODUCTION

Archie Cochrane, a British Epidemiologist, recognised that the people and organisations that wanted to make decisions about health care during the 1970s and early 1980s did not have ready access to reliable reviews of the available evidence¹. The first systematic review was produced in 1987.. This led to the creation of The Cochrane Collaboration. This is now a large well-resourced international organisation. With national centres that coordinate management, support and training, and several hundred-review groups, which coordinate studies in specific areas of pathology. The collaboration defines its work according to 10 key principles. Including collaboration, building on the enthusiasm of individuals, avoiding duplication, minimizing bias, keeping up to date, striving for relevance, promoting access, ensuring, quality, continuity and enabling wide participation in decision making.

The key features of a Cochrane review

The methodology is rigorous, systematic and repeatable². All literature published or not must be considered, as published literature is biased towards studies, which show a positive result. Rigorous attempts to identify unpublished trials and "grey literature", for instance conference proceedings, reports, theses, and manufacturers data must be made. Evidence is graded as to methodological quality, the gold standard being a well-conducted Randomised Controlled Trial. In order to facilitate quality assessment reporting of such a trial should follow the Consort³ The Cochrane review process excludes all but the highest quality, unbiased studies. In most studies in spite of an extensive literature search, only a handful of studies are of sufficient quality to be included.

Once studies are identified as an appropriate methodology, an objective appraisal of the standard of adherence is made. A predetermined proforma is used. Of interest are the inclusion criteria, and the drop out rate, the nature of the intervention and the outcome measures, which must be well defined. Scoring systems of methodological quality may be used; one example used in stroke care is the PEDro (physiotherapy evidence database)⁴ these may be summated to give a cut off score, although this does permit weighting of criteria. Criteria for methodological adherence include, random allocation to groups or treatments, concealed allocation, baseline similarity of groups on prognostic factors, blinding of all participants, blinding of those delivering intervention, blinding of all assessors, measures of at least one key outcome is obtained in 85% of the participants, initially allocated to groups, (intention to treat analysis), statistical comparisons are made between groups on at least one key outcome, there are both point measures and measures of variability for at least one key outcome.

Inclusion of papers into the review is based on agreement by two or more reviewers who are blinded to the others conclusions. There may be some merit in blinding as to authors and institution of studies. Reviewers must be aware of duplicate publication of the same trial, in the form of a conference abstract and full paper, and occasionally trials will be extended and republished, sometimes with different authors.

Combination of studies and secondary analysis may be performed under strict conditions if data is sufficiently comparable, and this may address the problem of small underpowered studies and type 2 errors. Meta analysis may be performed with **complete studies** may be combined using a specific methodology, or **individual patient data**. All reviews are expected to specify when they will update.

Problems with Rehabilitation Based Studies

Studies of rehabilitation interventions are a challenge to the Cochrane review process for a number of reasons. Rehabilitation interventions are heterogeneous. There is a lack of consensus about the best practice and theoretical approach, and rehabilitation populations tend to be heterogeneous. Much of the literature dates from a time before systematic reviews and the methodology is not as rigorous, including observational clinical studies, retrospective surveys. Many studies are small scale, un-funded, and there is no evidence of power calculations. The number of abstracts exceeds the number of published trials. This would be addressed in the future by more multi-centre research.

A COCHRANE REVIEW OF THE USE OF ORTHOTICS IN STROKE RATIONALE OF THE STUDY

Clinically, the effectiveness of orthoses to treat spasticity after stroke remains controversial. Some approaches suggest their use may prevent motor relearning⁵, or cause weakness in immobilised muscle groups. It is unclear at which stage of the natural history of the condition they should be used, the length of time the orthoses should be worn and, which type of orthosis best employed. It is unclear whether their effect is purely biomechanical, or whether there are tone-reducing properties.

DEFINING KEY TERMS

Stroke and other non-progressive lesions in the brain can cause both abnormalities of muscle tone in the arms and legs and a characteristic pattern of muscle weakness; this may lead to characteristic postural changes. In the lower limb there may be hip and knee straightening, downwards flexion of the ankle which may lead to slowing of walking and tripping. Weakness and inversion may affect stance. Immobility of joints affected by spasticity may cause pain in the joints and associated structures.

An orthosis is defined by the International Standards Organization as an externally applied device used to modify the structural or functional characteristics of the neuro-musculo-skeletal system⁶. For the purposes of the study it was specified a priori what constituted an orthosis. In the lower limb, all forms of thermoplastic or carbon fibre ankle foot orthosis, Valens and double upright calliper, Dynamic AFOs and dynamic insoles, Air stirrup braces, Serial Casting and Short leg splint. Excluded were Functional electrical stimulation, or hybrid including FES, Shoe lifts applied to the non paretic side, taping, Prolonged stretching without externally applied device and Studies of appliances done on test rigs with no patients involved

In the upper limb, included were dorsal splints, Volar splints, Elbow splints, Casting and Lycra Garments. Excluded were Items, which are not commercial splints, e.g. pads/ towels, taping, FES or FES hybrid orthoses, Interventions that are not primarily designed for control of arm posture and function, and Interventions for subluxed shoulder. (As this is the subject of a separate review.)

TYPES OF STUDY

All published and unpublished studies relevant to the use of orthotics in stroke and hemiplegia (N=130) were considered including abstracts, but excluding single case studies. These had to include patient assessment, and comparison data. Those considered in the third, assessment of methodological quality and data extraction phase included all un-confounded randomised controlled trials comparing the use of an orthotic device with usual care or in addition to usual care, or some other active intervention.

It was decided to permit all published and unpublished studies of individuals using a crossover methodology, or individuals acting as their own control, with and without orthotic device, providing there has been adequate randomisation in the allocation of sequence of treatment, adequate sampling, and or performed by blinded assessors, using rigorous methodology.

Types of participants

Any person with non-progressive cause of hemiparesis including stroke (including cerebral infarction, primary intracerebral haemorrhage, intraventricular haemorrhage or subarachnoid haemorrhage), central nervous system infection or tumour or traumatic brain injury. Childhood cerebral palsy, spinal cord pathology and hereditary spastic paraparesis are excluded. A second study to include childhood cerebral palsy is planned, and sensitivity analysis will be performed, to assess if these data sets are comparable.

Primary outcome measures: Increased angle of active or passive movement at joints a 50% improvement was deemed to be clinically significant. Spasticity, graded by Ashworth, and also EMG studies.

Secondary outcome measures: These include clinical/ biomechanical assessments of spasticity. Gait variables (e.g. Walking time and speed) including formal gait lab parameters (kinetic and kinematic data, physiological

cost index), pain, and incidence of contractures. Disability outcomes include personal and extended activities of daily living (including patient reported functional status), patient's satisfaction with splint/ acceptability to patients of intervention, the incidence of adverse effects and any quality of life data.

RESULTS

Findings of Search Process

The search strategy specified in our published Cochrane Protocol⁷ was performed, and the data from all published studies, including available conference abstracts are included in this report. Further review of unpublished postgraduate theses, manufacturers and developmental data are still required.

The initial search of electronic databases (stage 1) revealed 1843 abstracts of which 1713 were rejected as not relevant to stroke, spasticity, splinting or were duplicates. 130 abstracts remained and were reviewed. All those, which fulfilled the specification for study methodology, were included at this stage (stage 2). These were then subjected to further appraisal of methodological quality by independent data extraction by the two reviewers. Disagreements were resolved by discussion (stage 3).

Identification of Relevant Studies.

Lower limb studies (Included within Table 2) The following studies were identified as being Randomised controlled trials, Beckerman 1996⁸, Beckerman 1996⁸, Corry 1998⁹, Reiter 1998¹⁰, Wright 2002¹¹, and were then reviewed for methodological quality The study by Corry was excluded because it did not include adults, and that by Reiter because it only involved taping, which did not fulfil the criteria for an orthoses

The following studies included patients acting as their own control, and were identified as fulfilling all inclusion criteria. Chen et al 1999¹², Corcoran 1970¹³, Franceschini et al¹⁴ (possible duplicates include¹⁵: {Massucci, 2003 #1019}), Geboers 2002 (this trial uses alternate allocation rather than true randomisation^{16 17}, Rogers de Saca et al¹⁸, and Weiss¹⁹.

There were a number of studies, which fulfilled all the inclusion criteria apart from sufficient information about their selection or not including randomisation criteria; further information may be obtained from authors to permit later inclusion. Aggett 1999 and 2002 (same study)^{20 21}, Burdett 1988²², Danielsson and Sunnerhagen 2002²³, Gok and Kucukdeveci 2003^{24 25}, Hesse et al 1996 and 1999²⁶⁻²⁸, Lehmann 1987^{29 30} (no randomisation, the use of able bodied controls not relevant to predetermined research question), and Mojica 1988^{31, 32} Perriman and Coutts³³.

Other did not show objectivity of assessment, blinding or double assessment in measurement of outcome, De Witt 2003³⁴, Grissom and Blanton 2001³⁵, although information about inter-rater reliability was given, Tyson 1998 and Tyson and Thornton 2001^{36 37}. The manual interpretation of video results was not accepted unless there were two independent raters to provide adequate blinding. Adequacy of follow up and drop out rates were also considered. It was confirmed that statistical analysis had been performed

between the two groups of patients with and patients without the intervention.

Two studies gave insufficient information to appraise methodological quality particularly whether appropriate comparisons were made with the barefoot or shoes only state, Wong, 1991^{38,39} Wooley 1996⁴⁰, or what the methods of assessment were⁴¹.

UPPER LIMB

Six studies fulfilled the criteria of randomised controlled trials, or subjects acting as their own control for studies of the upper limb included Mills⁴⁴. Mathiowetz, Bolding, Trombly, C. A.⁴⁵, Gracies⁴⁶, Lannin⁴⁷, Poole⁴⁸ and Rose⁴⁹. Mills, Gracies and Mathiowetz were excluded, as their outcomes were not assessed in a blinded fashion.

The remaining three were further appraised for methodological quality; the first two are use of splinting in functional limbs, and the latter, use in paretic limbs. The first aims to include splinting within a rehabilitation programme, but the effect of the splinting may well have been overwhelmed by the active rehabilitation programme which was already going on. There is no evidence that any of the studies are sufficiently powered, the second shows no power calculations, and does not give background information about degree of hypertonus in the limbs or the stage of rehabilitation, it therefore does not define what the splinting is aiming to do. The third study is a simple impairment based study, which shows a reduction in hypertonus, but does not give a clinical or functional context. At this stage it does not appear that any of these will inform clinical practice.

Category of study	Numbers of studies	
Orthotics but irrelevant to stroke	5 (revealed by hand searching)	
Review articles	23 (Medline, Cinahl, Embase only) – 1 UL	
Randomised Controlled trial	7 Lower limb (10 papers one case of triplicate publication)	3 upper limb
“Cross over” studies, patients with and without orthoses acting as own control	21 studies Lower limb (27 papers - 3 cases of duplicate publication, one indexed twice with different author order)	5 upper limb without blinded assessor, 1 with insufficient randomisation.
Comparisons of types or conditions of AFOs	8 Lower limb	3 upper limb
Pure Biomechanical outcomes, no patient involvement	2 Lower limb	
“Clinical studies” including audit and qualitative data	13 Lower limb	21 upper limb
Single case studies	8 Lower limb	13 upper limb
Uncontrolled trials and observational studies	11 Lower limb	6 upper limb
Unable to review	3 lower limb	1 upper limb
Shoe lifts -	6 Lower limb	-
Total	80 Lower limb	54 upper limb

Table 1 Studies, which were considered for the study (for inclusion but not yet for methodological quality).

Author	Year	Title	Details of subjects	Outcome measures	Comment on methodological quality.
Beckerman, H. Becher, J. Lankhorst, G. J. Verbeek, A. L. M. Vogelaar, T. ⁴²	1996	The efficacy of thermo coagulation of the tibial nerve and a polypropylene ankle-foot orthosis on spasticity of the leg in stroke patients:	Placebo controlled RCT 2 x 2 factorial design. Tibial nerve blocking and AFO. 60 patients	Outcome = change in spasticity, tone, clonus, reflex, ROM, motor function of leg, balance	Well-designed study, non-compliance 30% with AFO and 50% with placebo AFO. Sample size of compliant population is similar to included papers. Analysis is by intention to treat.
Beckerman, H. Becher, J. Lankhorst, G. J. Verbeek, A. L. M. ⁸	1996	Walking ability of stroke patients: Efficacy of tibial nerve blocking and a polypropylene ankle-foot orthosis	Sixty stroke patients (17 women, 43 men)	Walking ability, walking speed	Same trial
Beckerman, Becher and Langhorst	1993	The efficacy of peripheral nerve blocking and a poly propylene ankle foot orthosis for hemiplegic patients	As above	As above	Same trial,
Chen, C. ¹²	1999	Anterior ankle-foot orthosis effects on postural stability in hemiplegic patients	24 splint users	Lateral weight shifting, weight bearing, postural sway, postural symmetry, and anterior-posterior weight shifting	Randomisation shown to group and order of assessment. Uses gait analysis and statistical comparison

Corcoran, ¹³	1970	Effects of plastic and metal leg braces on speed and energy cost of hemiparetic ambulation	15 hemi, users of AFO, only 13 could mobilise without brace	Energy consumption Walking speeds in different circumstances and on stairs Comfortable and maximal speed. Joint positions and calcaneal stability.	Good description of patient characteristics. Randomisation of order of testing. Well designed trial
Franceschini, et al ^{14,15}	2003	Effects of an ankle-foot orthosis on spatiotemporal Parameters and energy cost of hemiparetic gait.	9 chronic hemiparetic	6 minute walk, and 10m gait analysis, Significantly improved self-selected speed, Stride cycle, stance and double support and reduced energy Cost	Consecutive patients randomisation of order of trials, little detail about control trials. Objective measures repeated measures. Uses statistical analysis
	2002	Energy cost and gait assessment for hemiplegic walking: effects of an ankle-foot orthosis [sic]	9 chronic hemiplegic	Space-time parameters and decreasing energy cost Perry and Garret Walking Handicap Scale, basographic analysis, electromyography (EMG) and study of energy cost.	Further results from same trial is included
Gardner, ER ⁴³		Effects of short leg plaster casting on postural control of hemiplegic adults	10 subjects randomised	Standing balance and weight shifting, EMG,	Included. Does show randomised, does use objective EMG measures, and has shown statistical analysis. Casting included in the analysis. This is only an abstract
Massucci, M.	2003	Energy conservation in hemiplegic walking with Ankle-foot orthosis	9 chronic hemiplegic	Self selected speed, stride cycle, stance, and double support, and reduction of energy cost.	Same Trial
Rogers de Saca ¹⁸	1994	Immediate effects of the toe spreader on the tonic toe flexion reflex	18 adults,	Velocity Cadence Tonic toe flexor reflex using EMG	Randomised to all conditions, use of objective measures. Toe spreader included as mechanism of action is to reduce tone.
WEISS, WB, et al ¹⁹	2002	Rigid AFO impairs Walking ability in individuals with Hemi paresis from CVA	10 hemiplegics,	3 different AFO and without Velocity, stride length and cadence Joint angle Uses VICON gait analysis system.	Randomised order of testing interventions, controlled against shoes. Statistical analysis does give group means.
Wright P, Mann G, Swain I ¹¹	2002	Clinical Trial to compare electrical stimulation and the conventional ankle foot orthosis in the correction of drop foot following stroke	24 CVA patients (ongoing study). Randomly assigned to AFO or Odstock FES Stimulator.	Outcome = every 6 weeks assessed on walking speed, effort, endurance, spasticity, mobility	Included in appraisal for further analysis of methodological Quality

Table 2 Characteristics of included studies

Author	Year	Title	Details of subjects	Outcome measures	Reason for Inclusion or rejection
Lannin et al ⁴⁷	2003	Splinting the hand in the functional position after brain Impairment: a randomized controlled trial	17 subjects 14 completed 11 controls, Experimental Immobilising splint 12hrs per night	Length of the wrist and extrinsic finger Flexor muscles, Hand function - Motor Assessment Scale and pain VAS	Included, assessor blinded randomised controlled trial, good matching, No significant benefit, for splinting in addition to intensive rehabilitation programme.
Poole, J. L. C. ⁴⁸	1990	The effectiveness of inflatable pressure splints on motor function in stroke patients	8 CVA patients with hemiplegia. Matched pairs randomised	Pain, sensation, motor function	Included 30 minutes, 5 days a week, for 3 weeks Outcome assessment was blinded no sig diff
Rose, V. Shah, S ⁴⁹	1987	A comparative study on the immediate effects of hand orthoses on reduction (sic) of Hypertonus	30 patients post CVA less than 6 months. Randomised to treatment or non treatment	PROM, resistance to passive extension, force of spontaneous wrist flexion sig improve	Included randomised control trial, blinded assessment, using test rig Problems with wide group variability.

NB Paper by June 2002 has not yet been appraised ⁵⁰

Table 3 Characteristics of Included upper limb studies

PRELIMINARY ANALYSIS

The fourth stage of the Cochrane Review is further appraisal of methodology, and subsequent data extraction and secondary analysis.

General Methodological Points - Generalisability of results

Studies of lower limb orthotics, included mainly chronic stroke, which varied in duration from one month through to over 10 years, most had completed rehabilitation. Few studies discuss how they recruited patients into to the study. The majority of people recruited into studies were existing splint users. Time to familiarise themselves with the test device splints and this varied from 1 week to 6 weeks. Walking ability varied from 10 metres, to 6 minutes continuously. The age distribution included young strokes as well as older people. The mean age for participants is 60, which is younger than the general stroke population. Most studies excluded those with proprioceptive or sensory loss, a group that may particularly have mobility problems.

VARIABILITY OF STUDIES

Studies varied in their inclusion of the use of walking aids and whether they have spasticity, or contractures. None of the included studies looked at those who could stand and step and not mobilise. All studies use customised AFOs adjusted for optimal use, this may not reflect true clinical practice.

MEASUREMENT

Most incorporated studies use formal gait analysis, although others aim to include more real life obstacles such as stairs, and a longer course¹³ Spasticity was not included in any of the included studies.

A preliminary view of the included studies indicates the following observations. Most studies demonstrate an increase in walking speed related to use of an ankle foot orthosis, although the baseline tends to vary considerably

from around 15 metres per minute to 40 metres per minute. Studies have wide confidence intervals, which incorporate the possibility of a zero or negative effect. Both maximal speed and comfortable speeds may be used as outcome measures. Stride length again showed an increase in most studies, but with wide confidence intervals, which include the no change possibility. Cadence or number of steps per minute tends to show improvement only in some studies. Timing of double support is also reduced, although in some is confined to time of early heel strike. Reduction of postural sway is another positive outcome. AFOs which either allow free movement or are adjusted to permit Dorsiflexion are shown to be beneficial in gait parameter dorsiflexion is a positive outcome, and is improved both in stance and swing phase. Energy costs show a reduction although figures for millilitres of oxygen per kg per minute are very variable, and studies may be excluded on methodological ground, one study controls carefully for walking speed before measuring energy cost.

Methodological Problems from existing studies, which should inform future research

Greater efforts to ensure methodological rigour are needed, there need to be more standardised methods of classifying patients, according to functional level, and studies need to be done on specific groups of patients, and designed for them. For instance active users of lower limb splints may need to have a more challenging protocol, to demonstrate change in effect. Similarly there are few studies looking the use of splints in those with severe motor impairment, particularly those unable to mobilise. Existing studies of joint ranges of motion and spasticity lack methodological rigour, and the question about whether splints have a particular effect on tone and posture remains unanswered. Studies must be formed to look at "dosage of splintage". More work needs to be done on the timing of splinting interventions, and how it fits with the rehabilitation programme.

MEASURING OUTCOME

With upper limb studies the outcomes of treatment are not well defined, mechanisms of action in paretic and functional limbs may be different. The degree of motor control at the ankle is not measured routinely, and the question of whether there is adverse effect on power in antagonist muscles is not yet been adequately investigated. There is little evaluation of splint use in real life situations, for instance looking at functional mobility as in many of the studies of prosthetic usage in amputees (functional mobility scales). There are also no longer-term studies of splint usage

There is no study of upper limb orthotic, which is of sufficient quality to inform practice, the no particular type of splint shows superior efficacy, there is a heterogeneity of functional outcome measures, which makes studies impossible to compare, and too many studies are not rigorous

with their methodology. Many trials are based on clinical pragmatism rather than basic theory.

Future Randomised controlled trials should be on larger populations which are likely to be multi-centre, they may address the following;

- How early in rehabilitation should splints be used?
- Which subgroups of patients would benefit from the use of splints?
- Better functional outcomes at the activity and participation level?
- What is the mechanism of action of orthotic intervention?

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BIOMECHANICS OF UPPER LIMB ORTHOSES (S7-A)

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INTRODUCTION

Functional impairment of [parts of] the upper limb has many different expressions. Sound biomechanical analysis is at the basis of the management of the physical challenges involved. Orthoses are among the many treatment options. An orthosis can be defined as a mechanical construction intended to improve a functioning part of the human body where the anatomical structures are still present. Orthoses fulfill their task by the exertion of forces onto the anatomical structures. Depending on the upper limb segments involved, and depending on the functional requirements [i.e. static support only, or dynamical assistance of muscle functions] a specific pattern of forces between the orthosis and the body is needed. Therefore, no universal upper limb orthosis exists. Each functional loss, in combination with personal wishes and demands, results in a different orthotic design. However, every orthosis needs to fulfill some basic requirements concerning cosmesis, comfort, and control¹. Some examples of orthotic management of the upper limb are elucidated below.

THE WILMER SHOULDER ORTHOSIS

The WILMER shoulder orthosis is designed for brachial plexus patients and patients with hemiplegia who suffer a complete paralysed arm. The basic functions of the orthosis are the neutralization of a shoulder subluxation and the suppression of oedema by horizontal positioning of the forearm. The biomechanics of this orthosis has been described extensively by Cool². Here, the description is limited to the main features of the orthosis.

Because of cosmetics patients wish the orthosis could be worn underneath the clothing. That means neither the mitella nor the hemisling can be used. This is not regrettable, because both devices are unsuitable for the neutralization function. This can immediately be concluded out of the mechanics of the total orthotic system, Figure 1. Because the action line of the suspension force lies distally to the center of gravity of the bent arm no subluxation correcting force can exist. This conclusion paves the way to a proper structured orthosis. Displacement of the action line of the suspension force proximal to the center of gravity results in an attractive orthosis structure. The total system acts like a balanced arm, Figure 2. The weight of the forearm forces the upper arm upwards, thereby neutralizing a shoulder subluxation. One suspension point on the forearm is sufficient for the orthotic function described. This point is created by a tension band that suspends the arm on the shoulder. A shoulder cap transmits the suspension force to the body. A chest strap keeps the shoulder cap in place. All components are situated near the limb and therefore the orthosis can be worn underneath the clothing without problems. The WILMER orthosis, Figure 3, is the only device known that fulfils this task in reality. Here, it should be noted that subluxation orthoses that use a humeral cuff

to support the mass of the patient's arm are not capable of neutralizing the subluxation for a prolonged period of time. The humeral cuff supports the arm by friction forces on the skin only. Skin reacts to friction by creeping in a direction opposite to the friction force thereby trying to restore the normal skin position. As a consequence, the initial neutralizing action of the orthosis is lost.

The WILMER shoulder orthosis comprises the following advantages:

- effective neutralization of a shoulder subluxation
- suppression of oedema
- reduced pain
- reduced arm sway, therewith reducing the risk of possible injuries
- allows passive exo/endo rotation of the humerus
- light weight; the total mass of the orthosis is 200 g.
- comfortable to wear
- easy donning and doffing
- invisible to wear, underneath the clothing; which gives a cosmetic appearance

THE WILMER ADJUSTABLE SHOULDER ORTHOSIS

With the WILMER shoulder orthosis, clothing activities are sometimes found to be hampered by the orthosis because of the 90° flexed arm position. In order to facilitate donning and doffing of clothes, an adjustable version of the orthosis has been developed. By pushing against a knob that is located near the elbow in the suspension strap an unlocking action is performed. The arm with the orthosis can now be extended. Bringing the arm back in the 90° flexed position engages the lock again, enabling the orthosis to function. The working principle and the fitting procedure of this adjustable shoulder orthosis is exactly the same as for the standard version.

THE WILMER ELBOW ORTHOSIS

The WILMER elbow orthosis is a dynamic orthosis designed for patients with a paralysed elbow due to a brachial plexus injury or due to hemiplegia. A paralysed elbow can be brought into flexion by shoulder abduction angles over 90°. However, abduction angles that large are not acceptable both functionally and cosmetically. By adding an orthosis to the paralysed arm a decreased abduction angle necessary for full elbow flexion results, Figure 4. The top part of this figure indicates a simplified block diagram for the system paralysed elbow. The graph shows the switch to full elbow flexion at abduction angles over 90°. In the lower part of Figure 4 an orthosis is added. The orthosis offers a positive feedback as indicated in the block diagram where the orthosis output is added to the input abduction. This results in a decreased abduction angle necessary for full flexion. In practice the feedback is adjusted so that an abduction angle of approximately 30°

initiates elbow flexion. Smaller abduction angles do not result in elbow flexion.

The WILMER elbow orthosis, Figure 5, is a unilaterally construction with two hinged frame bars made from stainless steel tubing. It's very simple operating principle is understood quickly by patients. A new patient controls the orthosis correctly within a few minutes. Shortly thereafter he or she discovers dynamic control. The orthotic forearm can be positioned by an anteflexion pulse also. Patients master a quick hardly observable abduction/anteflexion upper arm control movement within the first hour of orthosis receipt. This quick learning process eliminates the clinical exercises non-appreciated by patients.

The orthosis is fitted to the patient's arm by two fittings on either side of the elbow joint. This way the orthosis only loads the skin with normal forces, not with shear forces. The fittings themselves are made from perforated plastic sheet material. In this way perspiration is not hampered. The fittings are supported only in their centre so they can automatically adapt themselves to the shape of the arm of the patient.

The body adaptive fittings are mounted in a frame. In orthopaedic practice two sided hinged frames are usual. Two sided hinges only work well when carefully aligned, symmetrically loaded and mounted to a rigid frame. In practice, these requirements are not fulfilled. Usually, the original poor alignment is worsened by a one sided locking mechanism. The two-sided hinges used in practice introduce high friction forces, leading to malfunction, noisy operation, wearing parts and a small time between failures.

A force analysis of elbow orthoses shows a one sided hinge to be free from torsion moment during normal operation. Also in the locked position a one sided hinged orthosis is only loaded in the rotation plane of the hinge. Moreover, one-sided hinged orthoses benefit cosmetics by its unilateral construction, figure 6, and favours the comfort of wearing by reduced weight and easy donning and doffing.

The orthosis is constructed out of stainless steel tubing. The unilateral frame bars are cold deformed oval for increased stiffness. In the compilation phase the fitting carriers can slide along the frame enabling their correct position to be determined experimentally. In the correct position found the fitting carriers are fixed to the frame. This time saving fitting procedure benefits costs.

A locking mechanism is added to the orthosis to enable the patient to retain the flail arm in the flexed position independent of the abduction/anteflexion angle. In this locked position the arm + orthosis is suitable to lift and carry objects. A second locking position at the near-extended arm enables pushing or clamping of objects. Moreover, this locked position is very useful donning and doffing the orthosis. The locking mechanism operates automatically and is controlled by the patient with his or her handicapped side. In figure 7 the operation cycle is illustrated.

The patient can flex and extend the elbow over the whole range of motion - from A to D - without interference of the locking mechanism. Only if he switches from flexion to extension in the small angle area indicated with C the locking mechanism will engage and lock the arm against extension in an approximate 90° flexed position. To unlock

the arm the patient has to flex the arm into area D. The lock in the near-extended position is engaged by a switch from extension to flexion in the small angle area indicated with B. An extension into area A unlocks the mechanism.

This locking mechanism can restrain some activities, like driving a car. Therefore, to prevent unexpected locking of the orthosis, the locking mechanism can be switched off by pulling a knob located at the wrist-region. A second pull engages the locking mechanism again.

The WILMER elbow orthosis comprises the following advantages:

- restores some elbow function
- comfortable to wear because of body adaptive perforated fitting areas
- light weight. A complete elbow orthosis weighs approximately 150 g.
- invisible to wear underneath the clothing at the medial side of the arm
- cosmetic appearance
- easy donning and doffing
- quick straight forward fitting procedure
- automatic locking mechanism

THE WILMER ELBOW ORTHOSIS FOR CHILDREN

For the youngest children with a partial or complete paralysis of an arm the WILMER elbow orthosis as described above is not suitable. The hinge and locking mechanism are too voluminous to be fitted on these children. In our experience the lower border is approximately 4 years of age. For children up to this age a separate elbow orthosis has been developed based on the same operating principle.

The orthosis, again, consists of two hinged bars with a spring attached in between them. Four fittings transfer the forces between the orthosis and the arm vice versa, similar to the WILMER elbow orthosis. No locking mechanism is incorporated. The weight of the orthosis depends to a large extent on the age of the child. It varies from 35 gram for a one-year-old child to 80 gram for a child of four years of age.

With this WILMER elbow orthosis for children the child can actively flex his or her arm again. It is possible to perform bimanual tasks in the whole range of motion of the arms. Therewith the possibilities to play and the development of the child are enhanced.

The fitting procedure is quite similar to the WILMER elbow orthosis. At least every six months the fitting and the spring need to be adjusted because of growth of the child.

THE WILMER ELBOW EXTENSION ORTHOSIS

Sometimes it is desired to assist the arm to extend. Various medical indications can be the basis of this desire, muscle spasm being the most frequent one. Based on the experience with the WILMER elbow flexion orthosis, an elbow extension orthosis has been developed.

The orthosis consists of two hinged bars, fixed on the arm with four perforated, body adaptive fittings. An adjustable spring mechanism extends the orthosis. Some active function can be achieved. By relaxing the muscles flexing the elbow, the orthosis will extend the arm.

UTX

The successful design of the WILMER elbow orthosis has been translated into an equally attractive and effective

knee-ankle-foot orthosis, known as the UTX³. This KAFO provides the user with a stable support of the leg during the stance phase, whereas the knee can swing free during the swing phase. Hence, the walking pattern is restored to almost normal.

CONCLUDING REMARKS

Basic biomechanical principles and a good understanding of the inevitable force patterns have resulted in the design of attractive and effective orthoses for the upper limb. The WILMER shoulder orthosis is the only orthosis known that neutralizes a shoulder subluxation. The WILMER elbow orthosis enables someone with a flail arm to actively flex and extend the elbow again, whereas the locking mechanism of the orthosis offers several functional advantages for the wearer.

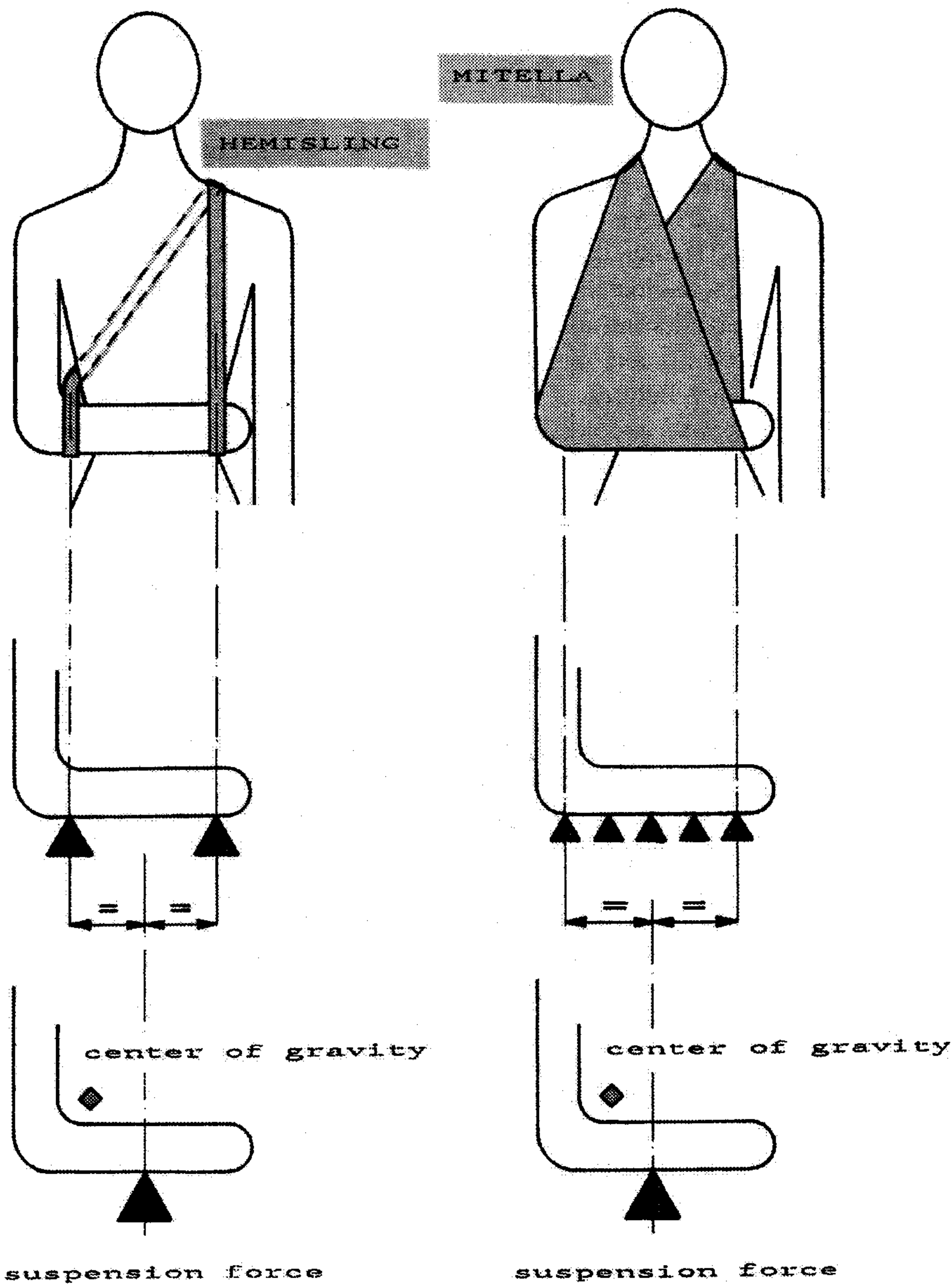


Figure 1. The action line of the effective suspension force of a mitella or a hemisling lies distally to the center of gravity of the bent arm. Therefore, no subluxation correcting force can exist.

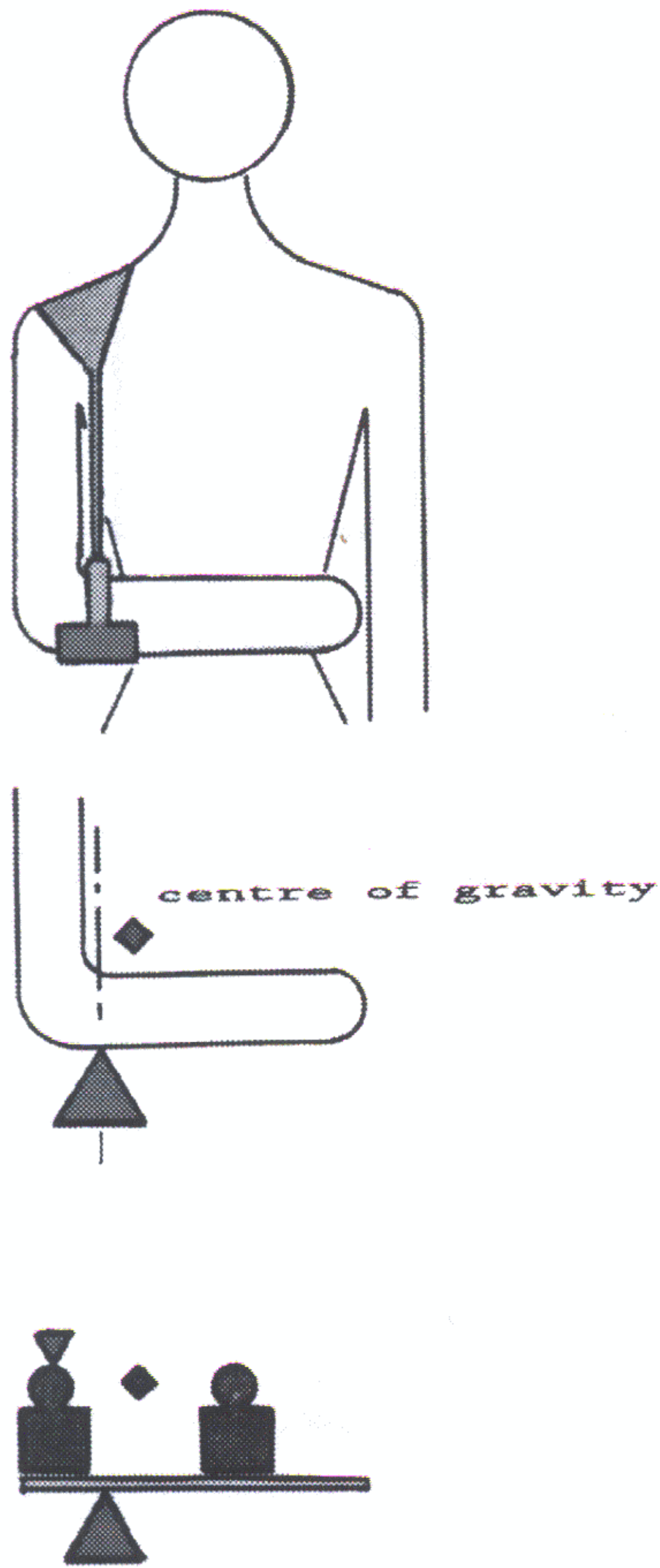


Figure 2. Displacement of the action line of the suspension force proximal to the center of gravity results in an attractive orthosis structure. The total system acts like a balanced arm. The forearm and hand together force the upper arm upwards into the shoulder joint.

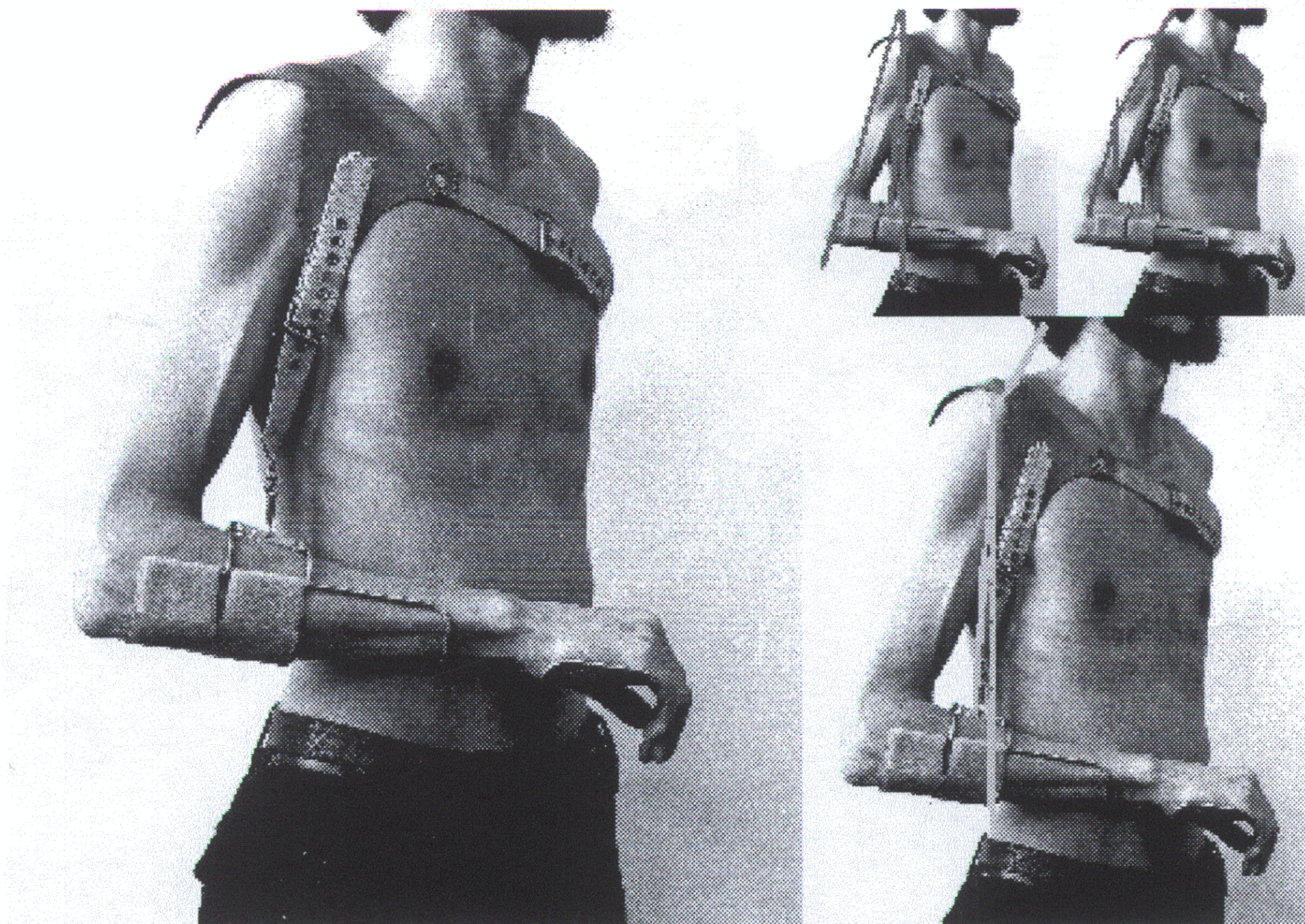


Figure 3. The WILMER shoulder orthosis, Figure 3a. In Figure 3b the forces acting on the sub-system of the forearm are shown. The force in the elbow returns in Figure 3c, where the forces acting on the sub-system of the upper arm are shown. For equilibrium a reaction force in the shoulder is needed. In Figure 3d, the subsystems of forearm and upper arm are combined to the system of the complete arm. The force in the elbow is now an internal force of the system. The resulting gravity force of the complete arm acts distally of the suspension force. The reaction force in the shoulder, the same as in Figure 3c, ensures the equilibrium of forces and indicates the successful neutralization of the subluxation.

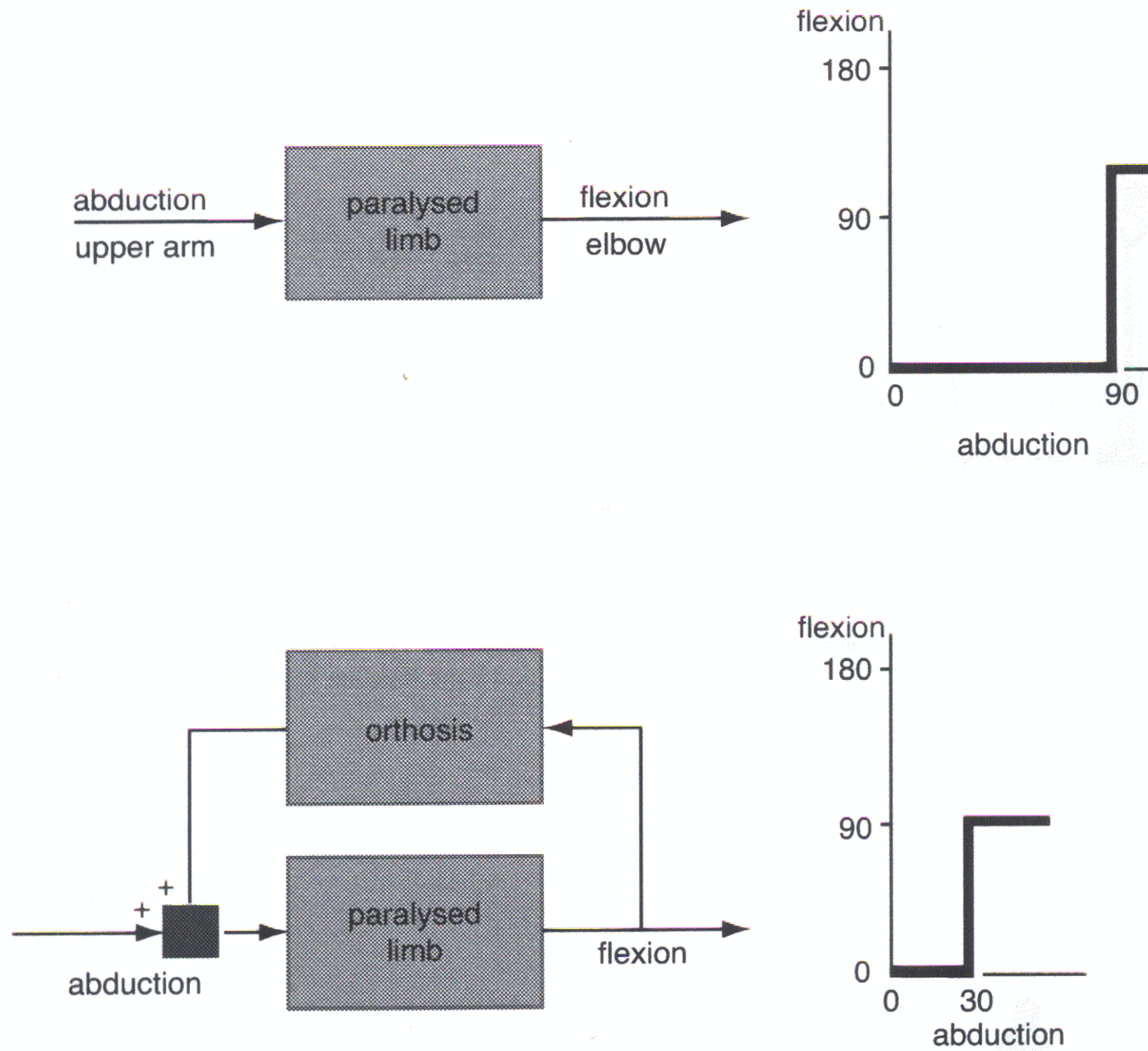


Figure 4. System analysis of a paralysed elbow. The top part of this figure indicates a simplified block diagram for the system paralysed elbow. The graph shows the switch to full elbow flexion at abduction angles over 90°. In the lower part of Figure 4 an orthosis is added. The orthosis offers a positive feedback as indicated in the block diagram where the orthosis output is added to the input abduction. This results in a decreased abduction angle necessary for full flexion.

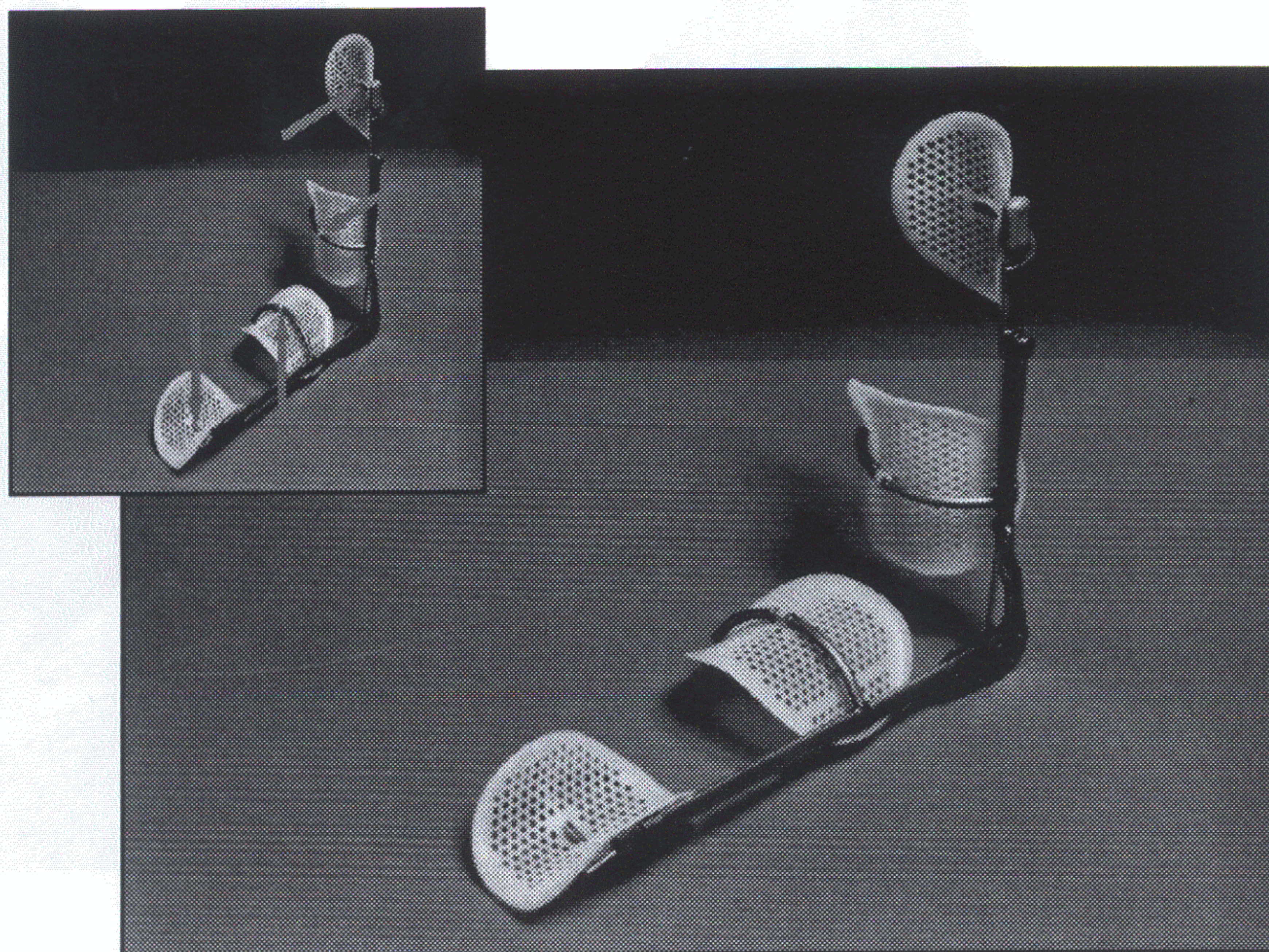


Figure 5. The WILMER elbow orthosis. The inset shows the forces on the four fittings during normal operation. As these forces act within one plane, parallel to the plane defined by the forearm frame bar and the upper arm frame bar, the unilateral hinge is free from torsional moments.



Figure 6. The WILMER elbow orthosis is worn at the medial side of the arm, thus enhancing cosmetics.

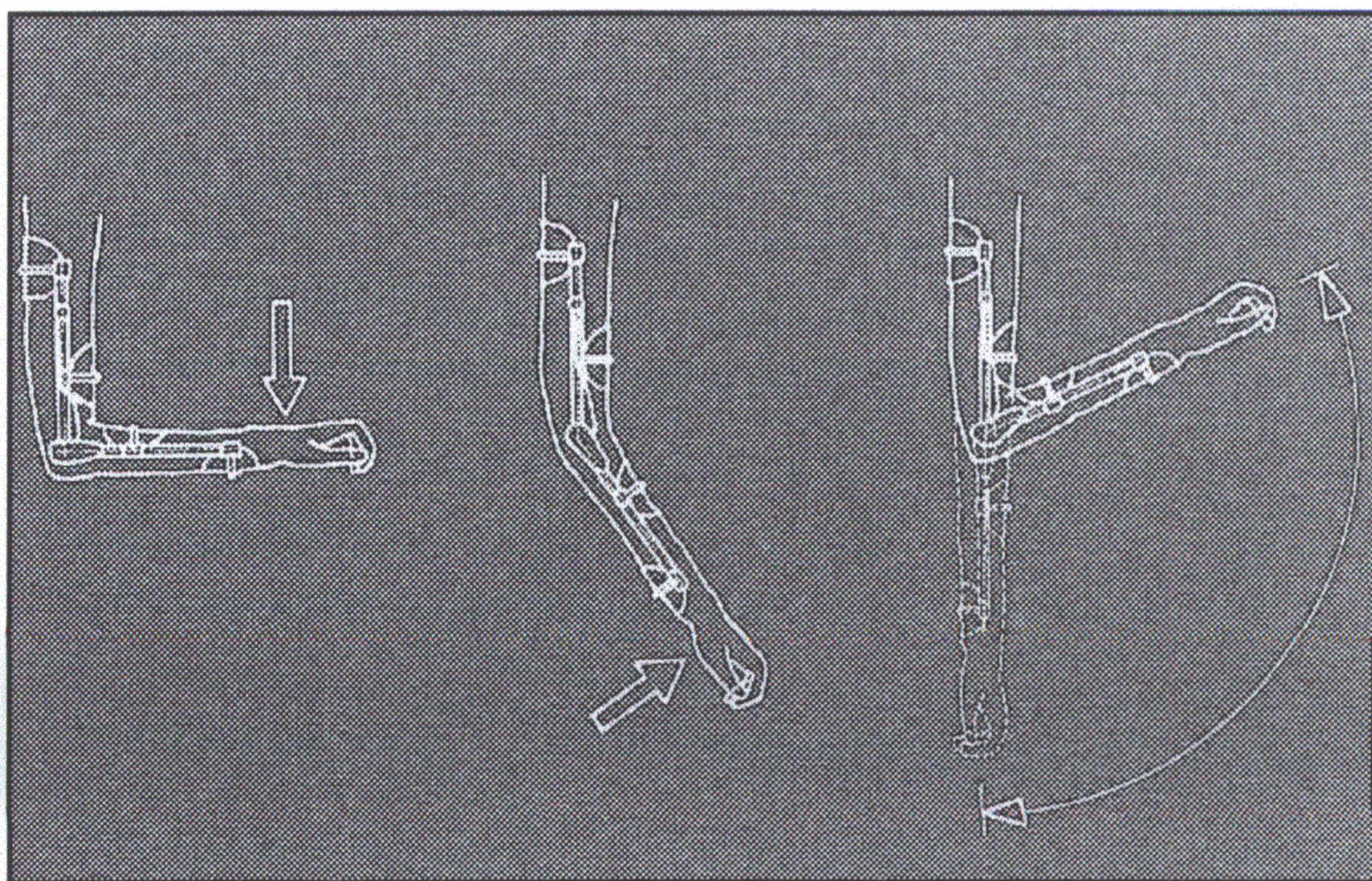
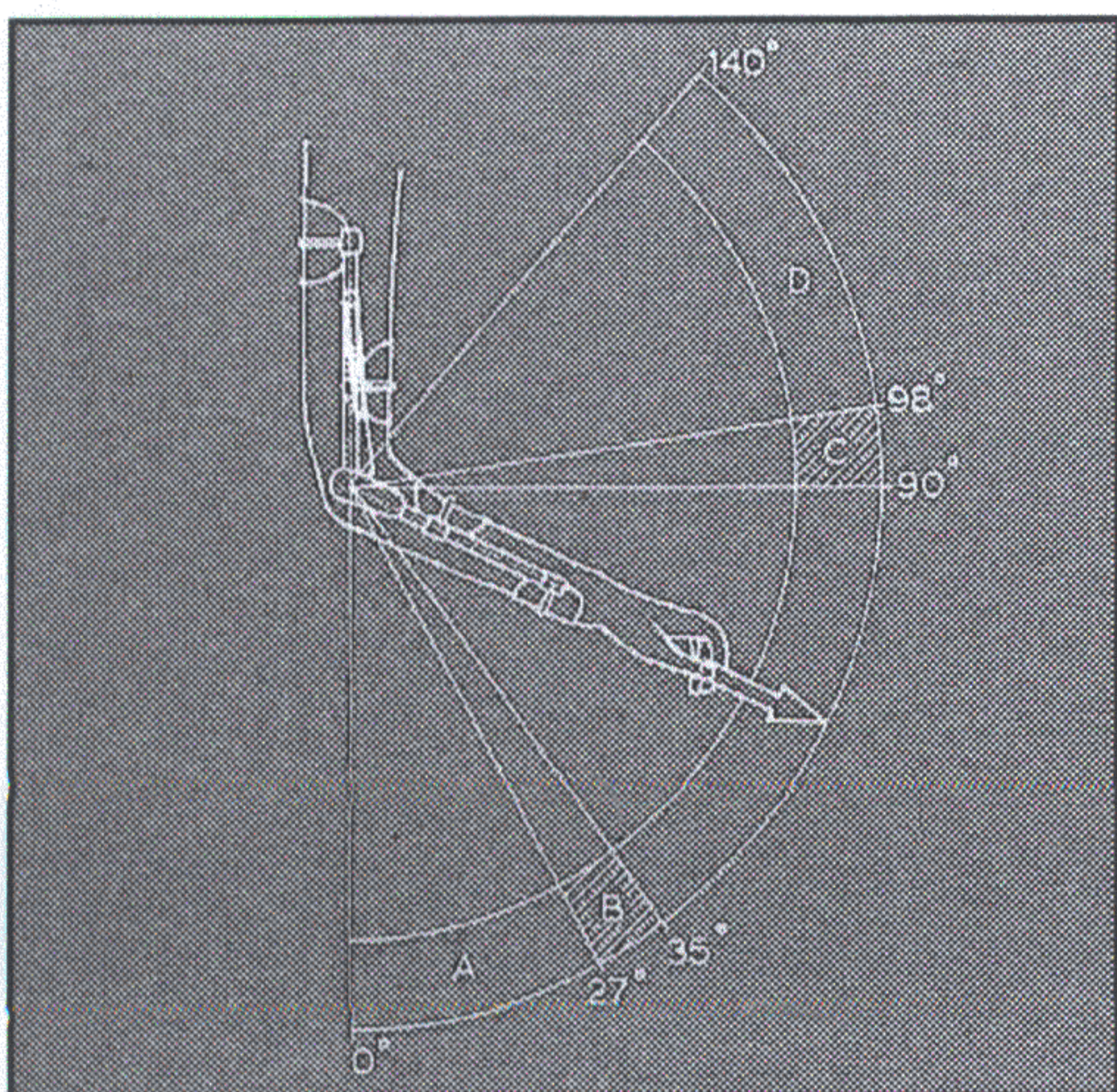


Figure 7. The operating cycle of the locking mechanism of the WILMER elbow orthosis

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BASIC BIOMECHANICS OF THE UPPER LIMB (S7-B)

Thomas V. DiBello CO

While our lower limb carries us into the world, our upper limb, with its ability to reach, grasp, hold and release, brings the world to us. As Neville Hogan describes in *Multiple Muscle Systems: Biomechanics and Movement Organization, Chapter 11*: "Several features distinguish upper limb function from that of the lower limb or whole body posture and balance:

1. The arm is the primary organ humans use to manipulate objects in the environment.
2. The function of the hands is as much sensory as it is motor.
3. The upper limb routinely interacts with a wide variety of physical objects. It must retain its stability and performance while doing so.
4. The human upper limb typically does not need to support the weight of the body; hence inherent muscle patterns designed to hold and stabilize an inverted pendulum system are rarely necessary, and concerns such as energy storage, energy transfer and joint loading take on less relative importance.
5. Rhythmic motion patterns typical of gait are less appropriate and less frequently observed."¹

Johnson explains that "the upper extremity can be examined as a linkage system. The main effector of the upper extremity is the hand; the wrist, elbow, and shoulder act to place the hand in space."² Light adds that "many activities that are perceived as simple hand functions actually arise from the integration of activities of the entire body, upper limb, and hand."³ For instance the patient with paraplegia and an unstable trunk must hook one arm over the back of the wheelchair to stabilize the torso before reaching with the opposite arm. As we begin our overview of upper limb biomechanics it is important to keep in mind the impact of each segment of the upper limb on the limbs function as a unit.

The Shoulder

As the most proximal joint in the upper limb the shoulder plays a primary role in limb orientation. Its substantial mobility is enhanced by the lack of restraint inherent in its boney configuration. The shoulder complex is formed by the scapulohumeral, acromioclavicular, and sternoclavicular joints. The joint itself is a ball and socket joint and is formed by the articulation of the head of the humerus and the glenoid fossa of the scapula. The entire mechanism is suspended from the trunk by soft tissue anchorage, with the only true skeletal articulation being the sternoclavicular joint.⁴ This orientation provides a high level of mobility; however the potential for instability is also high. Thus, the shoulder is prone to dislocation when its soft tissue constraints are disrupted and subluxation, particularly prevalent in the stroke patient, when muscle forces around the joint

have been disrupted by paralysis or weakness.

The basic movements of the shoulders' multi axial glenohumeral joint include: flexion and extension of 180° and hyperextension of 45° both in the sagittal plane, vertical abduction and adduction of 180° in the frontal plane, horizontal abduction and adduction of 135° as the arm moves across the front of the body in the coronal plane, and internal rotation and external rotation of 90° each with the elbow flexed and the forearm moving through the sagittal plane.⁵

The scapula and the muscles acting on it have a stabilizing and anchoring effect on the shoulder. Scapular movement can be described in terms of the change in the position of the scapula relative to the thorax. Scapular elevation and depression are thereby easily appreciated. Upward motion of the scapula, or elevation, is motion in which the inferior angle of the scapula moves anteriolaterally, tilting the articular surface of the glenoid upward. Downward scapular rotation, or depression, is the opposite- motion in which the inferior angle moves medially, tilting the articular surface of the glenoid downward. Scapular protraction is movement laterally and forward around the thorax. Scapular retraction is movement medially and back around the thorax.⁶

During the first 30° of shoulder abduction, often called the setting phase, scapulothoracic control is used to stabilize the scapula so that all abduction takes place at the glenohumeral joint. Through the arch from 30° to 180°, every 2° of glenohumeral motion is associated with 1° of scapulothoracic motion. Thus, in full abduction 130° of motion occurs at the glenohumeral joint and 50° at the scapulothoracic interface.⁷

In summary, we know the normal shoulder has a high degree of freedom. This allows the proximal end of the upper limb linkage system to position its distal segments through a large sphere of motion. The contact between the two articular surfaces in the joint are small, therefore – the glenohumeral articulation relies on capsular, ligamentous and the coordinated activity of nearly thirty muscles for its stability.

The Elbow

In contrast to the shoulder the elbow has a single degree of freedom: flexion and extension. Its limitation to this arc is governed primarily by the osseous contour of the olecranon and trochlea. Recurrent dislocation of such a constrained joint, acting through a single plane, is infrequent.⁸ The transverse axis of the elbow travels approximately through the trochlea and flexion and extension occur in the sagittal plane from 0° to 150°.⁹ Due to the configuration of the humeral trochlea, the forearm is aligned with the arm during flexion but is abducted when in extension, this is often referred to as the "carrying angle" and is of primary importance in upper extremity prosthetics.

The biceps has been termed the “feeding muscle” muscle since it both flexes the elbow and supinates the forearm to bring the hand to the mouth. The strength of the biceps should be sufficient to raise the forearm, hand and an object up against gravity. It is important that passive elbow extension be preserved in order to reach the perineum and active elbow extension, and triceps function, is necessary for overhead hand placement as well as more vigorous activities like using a wheelchair or walker.

In summary the elbow is a single axis joint that moves in flexion and extension. The elbow regulates the distance from the trunk to the hand during any given maneuver. This ability to alter the length of the limb is critical in activities such as feeding and perineal care.

The Forearm

The forearm governs the orientation of the hand in space and is comprised of the radius and ulna. Its three degrees of freedom permit forearm rotation, wrist flexion and extension and wrist deviation. The axis of rotation of the forearm runs diagonally through the head of the radius to the distal head of the ulna. Forearm rotation (pronation-supination) is 180°, in the transverse plane, when hand position is used as a reference point, and occurs as the radius rotates around the proximally stabilized ulna. During pronation and supination the distal end of the radius and the head of the ulna trace arcs of circles in opposite directions, but of equal lengths.¹⁰ At full pronation (palm down) the hand has rotated to a position where the dorsum is facing forward and is perpendicular to the midline, supination (palm up) represents rotation to a position where the palm of the hand is now facing forward and perpendicular to the midline. Pronation is the ideal position for body weight support. Supination is important in feeding and for the balancing of objects in the palm.

In summary the forearm is comprised of the radius and ulna and its actions include pronation and supination. These motions are important in performing many activities of daily living.

The Wrist

From a functional standpoint the wrist is a key joint. Its performance determines efficient digital performance. The wrist is a condyloid joint and its movement (flexion-extension and radial-ulnar deviation) occurs around two axes. Flexion of 80° and extension of 70° occur in the sagittal plane while radial deviation of 20° and ulnar deviation of 20° occur in the frontal plane. By a combination of these movements the wrist can circumduct to act as a universal joint.¹¹ Wrist dorsiflexion passively tightens the finger flexors by a tenodesis effect. As the wrist extends, the tendons and ligaments crossing the wrist and finger joints shorten, passively causing the finger joints to flex, resulting in the approximation of the tips of the thumb, index and forefinger. This finger posture or pinch is critical for grip activities.¹² Wrist position also determines grip strength. With hyperflexion of the wrist, the strength is diminished. In the precision grip (pinch) described above the squeezing power between the thumb and the index fingers maximal at

35° of wrist extension. It diminishes as the wrist is flexed or hyperextended. Most finger activities are performed with the wrist at neutral (35° extension) or in slight flexion.¹³

In summary the wrist is a condyloid joint that can move in flexion-extension and ulnar-radial deviation. By a combination of these movements it can circumfuse and act as a universal joint. Wrist position can cause a tenodesis effect of the fingers and can affect grip strength. Most finger activities are performed with the fingers in neutral or slight flexion.

The Hand and Fingers

Within the hand the metacarpophalangeal (MCP) joints of the fingers as well as the carpometacarpal (CM) joint of the thumb are the least constrained joints. This arrangement is analogous to the arm itself insofar as the most proximal joint is the least constrained and thus allows the distal segment to subtend the greatest arc. The distal interphalangeal (DIP) joint of the thumb and proximal (PIP) and distal interphalangeal joints of fingers two through five are limited to flexion and extension while the metacarpophalangeal joint of the thumb can flex and extend and, to a limited degree, rotate while the metacarpophalangeal joints of digits two through five can flex and extend and have a small amount of ab-adduction at full extension.^{14 15}

The hand has three arches: the longitudinal, the proximal transverse and the distal transverse. The integration of these structures creates a very stable structure.¹⁶

Functionally the hand is capable of prehensile and non-prehensile activities. Non-prehensile hand functions include the act of pushing an object, lifting an object with the opened hand or stirring an object with the open hand or a digit. Prehensile activities have been classified into two types: power and precision grip.¹⁷

In a power grip, a clamping force is produced by the flexed fingers against the counterpressure offered by the palm, thenar eminence, and distal thumb. To increase grip power, the thumb may be wrapped around the flexed fingers. In a precision grip, the object is held between the palmar or lateral aspects of the fingers and the opposing thumb. Stability is gained only through digital interplay.¹⁸

A power grip often requires the maintenance of a constant pressure on an object, while the actual movement of the object occurs as a result of the movement of the shoulder, elbow and wrist. Using a hammer to drive a nail is an example of a power grip. Conversely, in a precision grip manipulation of an object occurs with the fingers. Holding and moving a marble between the thumb, index and middle fingers while the shoulder, elbow and wrist remain still is an example of a precision grip.¹⁹

Precision prehensile activities can be further sub-classified as: palmar, tip and lateral pinch. Power prehensile activities are sub-classified as: cylindrical, spherical and hook grasps.²⁰

A typical prehensile sequence would include:

1. Positioning the hand over an object.
2. Opening of the digits around an object.
3. Closing of the digits around an object.

4. Manipulation of the object via arm movements, interdigital interplay or a combination of the above.
5. Opening of the digits to release the object.²¹

Finally one must appreciate that the sensory characteristics of the hand and fingers are very important to its effective function. The ability to sense hot and cold, rough and smooth along with visual cues and their integration with the brain affect our choice of prehension, grip type and force. The ability to "see" with our hands augments our vision and is an important part of the prehensile sequence described above.

In summary, the more proximal joints of the hand and fingers are the least constrained and act functionally to position the digits. The hand performs both prehensile and non-prehensile activities. Prehensile activities involve power and precision grips and six types have been identified.

Functional Range of Motion or the Joints of the Upper Limb

The amount movement of the upper limb movement needed to accomplish a variety of activities of daily living is an important criteria to appreciate when assessing the patient with upper limb pathology.

For instance, the functional range of elbow movement needed to perform a group of fifteen activities of daily living is 100° of the available 130°, ranging between 30° and 130°. In the forearm, of the available 180° only 50° of supination and 50° of pronation will achieve most important activities. At the wrist 40° each of flexion and extension and about 30° of ulnar and 10° of radial deviation are needed.²² In each instance and at every joint the functional range of motion is less than the maximal normal range.

CONCLUSION

The upper limb functions as a linkage system. Its full potential is best realized when it is able to work in concert with the entire body. The trunk gives the limb maximum stability while the shoulder gives it maximum mobility. The elbow regulates the distance an object is held from the body and the forearm and wrist regulate its orientation in space. The hand and fingers execute a series of complex highly coordinated actions to grip or move an object and its optimal function depends upon integration of sensory input both tactile and visual. In its totality then, the upper limb is a complex and highly efficient system that demands precise joint movement and coordinated muscle activity to achieve a desired function.

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ESTABLISHING A SCIENTIFIC BASIS FOR ORTHOTIC MANAGEMENT (R1)

James H Campbell PhD., CO

CREATING A CULTURE OF EVIDENCE:

This presentation will review, and comment on pertinent attempts made to ground orthotic management in a *culture of evidence*. In the past decade we have dramatically ratcheted up the debate over the quality and usefulness of evidence based research in Orthotics and Prosthetics. and there is increasing pressure on all of us to show results about treatment protocols and practices that work. There is a desire to direct efforts, and to place additional value on research-based evidence and less on intuition and experience.

However one of the real pleasures of being involved in orthotic management is that we are able to witness and contribute to the unfolding of a new science. In a recent editorial¹, and in the only document that this author could locate that specifically addressed the *state of the science* in orthotics and prosthetics, the author indicated that there is a desire to have logical and verifiable reasons for using one kind of technical component over another and a desire to

be more discerning with prescription choices through more objective judgments than are currently available. Orthotics and prosthetics has a low, or a best immature scientific content, however this is neither unique nor negative, but rather an exciting opportunity.

This review will contend that although published studies related to the efficacy of orthoses in stroke patients rank low in the hierarchy of levels of evidence, evidence exists to support the use of assistive devices, including orthoses. There is an obvious lack of high quality meta analyses, systematic reviews of Randomized Controlled Trials^{2,3,4} are uncommon and there are few high quality systematic reviews of case control or cohort studies. A sampling of pertinent published orthotic research reviewed by this author, Table 1, indicates that we have mainly relied upon case control or cohort studies (with a high risk of confounding or bias) and non analytical studies, e.g. case reports and case series to form our scientific base.

Rating of Study Design	Type of Study	Referenced Articles
1	Systematic Review and or meta analysis (where statistical techniques are used to pool the results of included studies)	
11a	Randomized Controlled Trial (with definitive results that do not overlap the threshold clinically significant effect)	
11b	Randomized Controlled Trial (with non definitive results i.e. a point estimate that suggests a clinically effective effect with confidence intervals that overlap the threshold clinically significant effect)	2,3,4
111	Cohort Studies (Two or more groups are selected on the basis of differences in their exposure to a particular agent and followed up to see how many in each group developed a particular disease or other outcome)	
1V	Case Control Studies (Patients with a particular disease or condition are identified and matched with controls, like cohort studies case control studies are generally concerned with the etiology of a disease)	
V	Cross Sectional Survey (Data are collected at a single time point but may refer retrospectively to health experiences in the past)	6, 7, 8, 9, 10, 12, 14, 20, 21
V1	Case Reports	11, 13, 15, 20
V11	Expert Opinion	1,5,16, 18, 19

Table 1. Systematic Review of Referenced Literature

Published studies related to the efficacy of orthoses in stroke patients rank low in the hierarchy of levels of evidence, evidence exists to support the use of assistive devices, including orthoses.

Grade of Recommendation: C

The desire is to follow the lead of the medical profession by relying more on well-crafted research to guide practice, to mirror attempts made by other allied health professions to set standards of quality for research and to synthesize what is known, or at least identify successful programs and practices, based on those standards.

Establishing Principles of Orthotic Design:

An orthoses, can be prescribed for a number of reasons and has been defined by the International Standards Organization as an external device used to modify the structural or functional characteristics of the neuromuscular and musculoskeletal systems.

To make an informed decision about whether a particular orthosis would be appropriate for a patient with gait dysfunction or functional limitation, rehabilitation professionals must understand two things⁵.

1. The basic biomechanical principles of joint motion
2. The underlying design of the orthosis and its impact on the joint.

A number of important questions are raised.

How and where does the orthoses apply force to provide stability or to control movement at a particular joint?

In what planes of movement does the orthosis have an effect?

Will it be most important for the orthosis to restrict movement completely or allow movement in a limited range, or will movement be assisted or unrestricted?

How does the application of an orthosis to control motion at one joint or limb segment impact those that are proximal or distal to it?

What impact does the orthosis have on each of the sub phases of gait?

Are the biomechanical tradeoffs or consequences imposed by the device outweighed by the benefits of its use, and if how is this determined?

Considering the patients physical condition and the possibility/probability for change in this condition what design of orthosis, or what types of orthotic materials, would be most appropriate?

Implementing Systematic Patient Assessment Strategies:

To develop an appropriate orthotic prescription there must be a thorough understanding of the patients diagnosis and prognosis⁵. A systematic examination of the musculoskeletal system identifies pertinent biomechanical or anatomical impairments, constraints or concerns that have an impact on choice of orthotic design and component selection.

Examination of the neuromuscular system provides information about abnormalities of tone, sensory impairment,

compromised postural control and difficulty with motor control. As we attempt to establish a scientific base and develop a strong technical structure for the orthotic management of the lower extremity of stroke patients a top down analysis of gait could be considered appropriate. The process that we are most interested in starts as a nerve impulse in the central nervous system and ends with the generation of ground reaction forces. The key feature of this approach is that it is based upon cause and effect.

Skin condition and integrity are examined to assess the ability of skin tissue to withstand force.

Restoration of walking and examining the Characteristics of Gait after stroke:

Good science should be aimed at emphasizing and explaining underlying causes rather than merely observing output phenomena, the effects, in some vague and unstructured manner. Establishing a scientific basis for orthotic management begins when we create a structural framework, or model, that helps us understand and measure orthotic intervention and the application of orthoses. Several researchers^{6, 7,8,9,10,11,12,13,14,15} have measured the efficacy of orthotic management in stroke by applying observational and quantitative gait assessment techniques.

Walking is the primary goal of patients with stroke¹⁶ as well as their families and rehabilitation professionals, many aspects of gait are compromised after stroke but achieving independence is more important than recovering a normal gait pattern.

The improvement of gait ability is a major aspect of rehabilitation after stroke^{6,7} its outcome is often decisive for the vocational and social reintegration of the patients. Patients themselves, when asked for their priorities, ranked the restoration of walking as one of the most important goals during their rehabilitation program. Hesse^{6,7,17} focused on the evaluation of gait after stroke commenting on the applicability of internationally established outcome scores and assessment instruments. Gait analysis helps us to understand the ways in which musculoskeletal and neuromuscular impairments compromise the patients mobility and functional status.

Dittmer et al¹⁸ states that the use of orthoses to improve the gait of hemiplegic patients is a common rehabilitation practice. In an attempt to measure orthoses effectiveness he accepted the view of Mizrahi et al.¹⁰ who identified improvement in walking speed as the most effective method to monitor improvements in gait of hemiplegic patients claiming that an effective orthosis (for stroke patients) would allow greater cadence (number of steps per minute) than one of an inferior design. Therefore any evaluation on the effectiveness of an orthoses in correcting hemiparetic gait should be based upon improvements from the *normal* gait pattern exhibited by hemiplegics.

Functional Assessment:

Understanding and consideration of a patients functional status and functional limitation is important, an orthosis that may be deemed mechanically effective but prevents the wearer from accomplishing important tasks and activities,

patients value function over quality of movement, suggesting that measured kinematics or bio mechanical improvements should be taken in context. Further research that compares quality of movement with functional mobility is acknowledged as crucial. This is equally important when considering the orthotic management of the upper extremity in stroke patients, a subject of significant investigation and some controversy^{19,20}. A follow up survey²¹ examined the use of shoulder supports, conducted in Canada the review underlined the need to establish the scientific base for occupational therapy in all areas of practice but specifically stroke management.

Role of Consensus conferences, professional associations, organizations and component manufacturers:

In 1976 the United States Congress became alarmed at the rapid increase in health care costs. In response the National Institute of Health established a new mechanism to identify and assess the safety and efficacy of new medical technologies. These **consensus development conferences** generally focused on a specific technology such as magnetic resonance imaging or dental implants. The conferences were exclusively composed of experts and after 3-4 full days of deliberation produced a detailed and comprehensive analysis of the technology in question, including full references, an assessment of the quality of the data available and an explanation of the way in which differences of opinion were resolved. The model became widely used not just in the US, but also in European countries, such as Sweden and the Netherlands. By 1995 over 100 medical consensus conferences had taken place in Europe.

The International Society for Prosthetics and Orthotics (ISPO) acts as a vehicle for the exchange of information through such means as publication of its journal and the organization of seminars, courses and conferences,

The American Academy of Orthotists and Prosthetists (AAOP) publicly subscribe to the idea that the ultimate purpose of a professional association is to develop a knowledge base that will maximize the effectiveness of practice.

Both ISPO and AAOP have observed the success of the **consensus development conference** model, in the last 5 years ISPO have sponsored 4 and AAOP 2 such conferences.

In the long run the companies that market orthotic products also will have to take some responsibility for investing in clinical trials and evaluations. The time will come when it will become a distinct marketing advantage. Until now, there's been little incentive for those marketing orthotic products to pay for studies of their effectiveness.

Summary:

The reason, I think, for the cry for more research and better research is to delay implementing the research that we have, said David C. Berliner, a professor of education at Arizona State University in Tempe. The idea that we can shift immediately to only things that are justified by research is super-ambitious and, probably, a fantasy.

There is a desire to direct efforts, and to place additional value on research-based evidence and less on intuition and experience. It is necessary to have standardized approaches and harmonized definitions of concepts and specialized terms. To carry out more research, and to put into operation what is learnt, it is necessary to have trained people and professional associations must continue to lead in setting evidence based practice as a priority.

Published studies related to the efficacy of orthoses in stroke patients rank low in the hierarchy of levels of evidence, but evidence does exist to support the use of assistive devices, including orthoses. Relating to the lower extremity, further research that compares quality of movement with functional mobility is acknowledged as being critically important.

Questions/Discussion:

1. What role can gait analyses and internationally established outcome scores and assessment instruments play in assessing the efficacy of orthotic management?
2. Can we enforce a requirement that individuals involved in the provision of orthotic management use only research-based programs and practices?
3. Does enough good research exist for individuals involved in orthotics to use, and in a form that's usable and what is the value of case studies and other qualitative research?

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NON-ARTICULATED ANKLE-FOOT ORTHOSES (R2)

Robert James Bowers

INTRODUCTION

The papers in this review have been sourced using the RECAL information database of the National Centre for Training and Education in Prosthetics and Orthotics, University of Strathclyde. RECAL is the world's most comprehensive bibliographic database on the topics of prosthetics, orthotics and related rehabilitation engineering, and has access to over 65,000 articles in the field. In addition to listing the article title, author, journal details and abstract, all references are prepared with keywords that facilitate the location of papers on specific aspects of treatment. The results of searches relating to the rehabilitation of patients with stroke are telling, when compared to other pathologies. Searching the database for the keyword "stroke" produces 2556 results, while searching for the term "cerebral palsy" produces a comparable 2122 results. However, when the keywords "Ankle-foot orthosis" (AFO) are added to the "stroke" search, the number of results reduces to a mere 41 (compared to 104 for "ankle-foot orthosis and cerebral palsy"). This is indicative of the dearth of research material in the field.

Methods

After first identifying the recognised effects of stroke-related hemiplegia on the gait of those affected, this review will list and rank the published material on a range of non-articulated ankle-foot orthoses that have been used to address each of the individual gait problems that may be encountered. In this way the reader may relate the specific problems affecting individual patients, to the evidence available for orthotic treatment using non-articulating ankle-foot orthoses. In the context of this review, a "non-articulated ankle-foot orthosis" is defined as a one-piece ankle-foot orthosis, that has been constructed without the incorporation of a mechanical ankle joint, but which may either be rigid, or may permit some movement due to the flexibility of the material used.

The effects of stroke-related hemiparesis on the gait of affected persons are profound. Hemiparetic gait has been characterized as slow and stiff, with poorly coordinated movements that lead to primary and compensatory gait deviations and a considerable increase in energy cost (Lehmann et al ¹ 1987). Some of the observed abnormalities may be explained by the very slowness of the gait of the hemiplegic. For example, it is observed that in the able-bodied, a reduction in walking speed is associated with reduced cadence and step length, both of which are common features of stroke gait.

There are, however, other characteristics of hemiplegic gait that are independent of walking speed, and which are directly related to faulty biomechanics. Hemiparetic gait is markedly asymmetrical, with the step-length of the affected limb being greater than that of the unaffected side. There is also asymmetry in the duration of the swing and

stance phases, with a shorter stance and longer swing being observed on the affected side, and a reluctance to bear weight through the affected limb. Initial contact of the foot on the ground typically occurs with the lateral aspect of the forefoot, due to tone-induced equino-varus deformity. Knee recurvatum in mid to late stance is common, due to the fact that the ground reaction force is typically further anterior to the knee than normal, and tibial progression in second rocker is impeded by the more plantarflexed position of the foot. The abnormally flexed alignment of the hip throughout stance is another contributing factor to the anterior placement of the ground reaction force. In swing, knee flexion and ankle dorsiflexion are reduced, with hip circumduction the compensatory mechanism commonly employed to aid ground clearance. There is a tendency to supination of the foot in both swing and stance, with an adducted position of the forefoot, which in stance may contribute to the generation of varus moments at the knee.

Findings of the literature review

AFO effect on the energy cost of gait

The energy cost of hemiplegic gait is higher than that of able-bodied subjects, and a number of authors have investigated the effects of AFO use on oxygen consumption and energy expenditure. Corcoran et al ² (1970) tested hemiplegic subjects using either a conventional metal below-knee orthosis or a plastic ankle-foot orthosis, and reported a reduction in oxygen consumption with both orthoses when compared to the unbraced condition. There was, interestingly, no significant difference between the results obtained with the metal orthosis and the plastic orthosis. Significantly, both types of orthosis positioned the talocrural joint of the subjects in the same alignment, equating to 10 degrees of anterior inclination of the tibia, which approximates the angle achieved in normal gait. Danielson et al ³ (2002) reported a significant reduction in oxygen consumption in patients fitted with a carbon fibre ankle-foot orthosis, while Franceschini et al ⁴ (2001) also reported a decrease in oxygen consumption in patients fitted with custom plastic AFOs. Dacso et al ⁵ (1963) reported a reduction in energy expenditure (expressed as calories/min/kg) of the order of 28.4% in subjects who received an ankle-foot orthosis and training, although the type of orthosis is not described.

GRADE OF RECOMMENDATION C

AFO effect on walking speed and cadence

Many researchers have investigated the effect of a variety of designs of ankle-foot orthoses on the walking speed of stroke patients, with evidence of improvement reported by a number of authors. Franceschini et al ⁴ (2001) reports improvement in walking velocity in patients treated with a custom-made solid ankle polypropylene AFO, as do Corcoran et al ² (1970) Weiss et al ⁶ (2002) and Beckerman et al

⁷(1996) and Lehmann et al ¹(1987) with a non-articulating metal AFO. It is important to note that if the ankle joint is to be immobilised in a rigid AFO, the angle at which it is held is critical, if bending moments about the knee are to be normalised and progression through stance phase is not to be impeded. Lehmann et al ¹(1987) fitted patients with a rigid metal ankle-foot orthosis in two different alignments, 5 degrees of plantarflexion and 5 degrees of dorsiflexion. He observed improvements in gait velocity with both orthosis variants, but it is significant to note that there was a statistically greater improvement with the dorsiflexed alignment. Corcoran et al ²(1970) reported improvement in walking speed with either a metal or a plastic AFO, both of which held the ankle in an alignment of 10° anterior tibial inclination, and found no significant difference between the results obtained with the different types of orthosis. In this respect it is interesting to consider the paper by Weiss et al ⁶(2002), who reported that improvements in gait speed were less with a rigid plastic AFO than with an articulating plastic AFO. The angle of anterior alignment of the tibia in the rigid AFO in this study was reported as 5 degrees, which is less than the angle achieved in normal gait, and less than that advocated by Corcoran et al ². This may account for the fact that the patients who were fitted with alternative orthoses that did not restrict dorsiflexion, were able to walk faster. Beckerman et al ⁷(1996) found a small but statistically insignificant improvement in walking speed in patients fitted with a rigid plastic AFO in 5 degrees of anterior tibial tilt. Beach et al ⁸(1999) compared a polypropylene solid ankle AFO with a similar design made from thermoplastic elastomer (TPE) and reported walking speed closer to normal with the TPE orthosis. A number of authors report on the use of Dynamic Ankle-foot Orthoses (DAFOs). Mueller et al ⁹(1992) reports improvement in gait speed using a DAFO, while Diamond et al ¹⁰(1990) and Dieli et al ¹¹(1997), independently report improvements in walking speed that were greater when using a DAFO than with a posterior leaf spring (PLS), an orthosis that is typically not custom made for an individual patient, and one that may be considered inappropriate in the presence of spasticity. Iwata et al ¹²(2003) reported improvement in walking speed with a modified PLS device. Burdett et al ¹³(1988) and Aggett¹⁴(2002) found that walking velocity was unchanged with the Air Stirrup™ brace.

As has been previously mentioned, cadence is typically related to walking speed, so orthoses that bring about improvements in gait velocity may be expected to also improve cadence. Dieli et al ¹¹(1997) reported an improvement in cadence when using a DAFO, while Iwata et al ¹²(2003) reported improvement in cadence following modification of a PLS device by the addition of an inhibitor bar in the treatment of patients with tonic toe flexion reflex.

GRADE OF RECOMMENDATION C

AFO effect on step length

Most investigations into the effect of ankle-foot orthoses on step length have produced positive results. Lehmann et al ¹(1987) found that a metal solid ankle-foot orthosis increased step length, while increases in step length were

also found by Mojica et al ¹⁵(1998) using plastic AFOs, Iwata et al ¹²(2003) who reported an increase of 8% using a modified PLS, and Oshawa et al ¹⁶(1992) with a thermo-plastic design known as the FAFO2. Beach et al ⁸(1999) found that an ankle-foot orthosis made from thermoplastic elastomer (TPE) improved step length more than a plastic solid ankle-foot orthosis. Dieli et al ¹¹(1997) and Diamond et al ¹⁰(1990) found that step length was improved by both a DAFO and a PLS, with the DAFO producing better results. Burdett et al ¹³(1988) reported improvements with both a plastic AFO and the Air Stirrup™ brace, while Aggett ¹⁴(2002) reported that step length was unchanged with the Air Stirrup™ brace.

GRADE OF RECOMMENDATION C

AFO effect on gait asymmetry

Improvements in symmetry of gait were reported by Franceschini et al ⁴(2001) with a custom-made solid ankle polypropylene AFO, and Lehmann et al ¹(1987) who used a metal solid ankle-foot orthosis. Diamond et al ¹⁰(1990) found that gait symmetry was improved by both a DAFO and a PLS, as did Dieli et al ¹¹(1997) who reported greater success when using the DAFO.

GRADE OF RECOMMENDATION C

AFO effect on weightbearing through the affected limb.

Chen et al ¹⁷(1999) reported a significant improvement in weightbearing through the hemiparetic limb in a series of 24 patients fitted with an anterior AFO. Dieli et al ¹¹(1997) reported better success when using the DAFO rather than the PLS. Franceschini et al ⁴(2001) and Mojica et al ¹⁵(1998) had success with custom-made solid ankle polypropylene AFOs, while Mueller et al ⁹(1992) reports improvement using a DAFO.

GRADE OF RECOMMENDATION C

AFO effect on equinus of the foot and swing phase ground clearance.

Flaccid equinus of the foot is, orthotically, simple to address. Aggett ¹⁴(2002) reported that equinus was reduced with the Air Stirrup™ as did Burdett et al ¹³(1988) who reported even better improvement when using a plastic AFO. Dieli et al ¹¹(1997) reported greater success when using the DAFO, rather than the PLS. While flaccid plantarflexion of the foot is encountered, equinus of the foot in stroke is often exacerbated by the presence of high tone in the plantarflexor muscles. In such cases, a greater degree of rigidity is indicated in the ankle-foot orthosis. Beckerman et al ⁷(1996) reported control of equinus using a rigid plastic AFO, as did Oshawa et al ¹⁶(1992) with the FAFO2. A surprising number of papers made no reference to control of the equinus foot.

GRADE OF RECOMMENDATION C

AFO effect on knee recurvatum.

The ability to prevent stance phase plantarflexion is important if knee recurvatum is to be controlled using an ankle-foot orthosis. Lehmann et al ¹(1987) was successful

in controlling recurvatum using a metal solid ankle-foot orthosis set in 5° dorsiflexion. Miyazaki et al¹⁸ (1997) found that a dorsiflexion angle of 7° ensured good results, while Oshawa et al¹⁶ (1992) recommended 10° in the FAFO2 design. The normalisation of bending moments about the knee is essential in the control of knee recurvatum, as well as in ensuring the effective forward progression of the body over the affected limb.

GRADE OF RECOMMENDATION C

AFO effect on hip flexion

No reference was found that reported on the influence of an ankle-foot orthosis on the hip joint of the affected side.

GRADE OF RECOMMENDATION NO EVIDENCE

AFO effect on supination of the foot

Aggett¹⁴ (2002) reported that varus angulation of the subtalar joint was reduced with the Air Stirrup™, as did Burdett et al¹³ (1988) who further reported that while the orthosis reduced the varus, it did not fully correct it. Varus was successfully controlled by a rigid AFO in the study by Beckerman et al⁷ (1996), by a DAFO in the study by Dieli et al¹¹ (1997), and by the FAFO2 design described by Oshawa et al¹⁶ (1992). A surprising number of papers made no explicit reference to control of the varus foot.

GRADE OF RECOMMENDATION C

AFO effect on spasticity

Beckerman et al¹⁹ (1996) reported no effect on spasticity that could be attributed to the use of a rigid polypropylene AFO. No evidence for reduction in spasticity was offered by any of the papers advocating the use of DAFOs. Although not a measure of spasticity, EMG studies on patients fitted with the FAFO2 design described by Oshawa et al¹⁶ (1992) showed a reduction in activity of the gastrocnemius and hamstrings. An interesting finding was that Iwata et al¹² (2003) reported improvement in cadence following modification of a PLS device by the addition of an inhibitor bar in the treatment of patients with tonic toe flexion reflex, suggesting a change in neuromuscular activity. It was surprising to note the prescription of PLS orthoses in some cases where spasticity had been reported, as this is a known contraindication for this device.

GRADE OF RECOMMENDATION NO EVIDENCE

DISCUSSION

Perhaps the most striking feature of this review of literature on the use of non-articulating ankle-foot orthoses in the treatment of stroke is the paucity of literature available for review and more specifically, the lack of material available at the higher levels of evidence. This clearly indicates the need for more research, particularly at the higher levels. Despite the fact that the levels of evidence of the reviewed material are low, a reasonable number of papers have been identified which support the use of non-articulating ankle-foot orthoses in the management of a wide range of functional problems. The fact that success has been achieved using a variety of different orthotic designs, reinforces the point that the application of sound orthotic principles aimed at identification and treatment of specific functional

problems is what is important, and that no single type of orthosis will ensure success. Inappropriate prescription of an orthosis will produce disappointing results, for example the use of the PLS orthosis in the presence of high tone, of the fitting of solid AFOs in which the angle of tibial inclination is inappropriate.

Only two published papers at the level of “randomised control trial” were identified (the 1996 papers from Beckerman et al.^{7,19}). As the only randomised control trials, the Beckerman papers inevitably acquire a significance that other papers do not, and consequently they may be cited to influence prescription practices in many countries. It should therefore be pointed out that the work is not without its faults. The work compared the gait of hemiplegic subjects using a solid polypropylene ankle-foot orthosis, with a group using what the authors described as a “placebo AFO” (in effect a jointed plastic AFO with no resistance to plantarflexion or dorsiflexion). This concept of a “placebo AFO” is surely an oxymoron, for even an AFO that allows free plantarflexion and dorsiflexion can still exert an important influence on the alignment and movement of the foot and ankle in both the coronal plane (a fact that was acknowledged by the authors) and also the transverse plane. It was notable that control of the transverse plane component of equinovarus gait is an issue that receives scant attention in the literature relating to stroke. It cannot be reasonably claimed that such an orthosis has no effect, and it is therefore not a true placebo. Although the patient group treated with the “true” AFO showed improvements in both the “ambulation” category of the Sickness Impact Profile (SIP) score, and gait velocity, neither was reported as statistically significant, and it may be that the SIP is too insensitive to the changes occurring. Another cause of concern was the high number of patients reporting adverse effects of orthotic treatment. Forty-four of 60 subjects had complaints about the orthosis supplied, and there was a reported non-compliance rate of 50%. It is however, to the authors’ credit that they record and report the adverse effects of treatment, as most authors fail to mention these. In a review by Johnston et al²⁰ (1994) of stroke patients fitted with ankle-foot orthoses it was reported that 26.3% made no use of the devices. However, those patients with slower gait, those regarded as less safe walkers, those considered more disabled (assessed using the Functional Independence Measure) and those with impairment of proprioception made considerably better use of their AFOs. Milani et al²¹ (2001) reviewed 18 patients who had been fitted with AFOs (9 custom and 9 prefabricated). Significantly, satisfaction with comfort was 41.7% in the prefabricated group and 88.9% in the custom group, while satisfaction with walking ability was 58.3% in the prefabricated group and 100% in the custom group. This should raise questions about the common practice of supplying prefabricated AFOs to this patient group.

A disappointing number of papers fail to give detailed information on the design of the ankle-foot orthoses being prescribed, particularly regarding the angle at which the tibia was aligned by the device, despite the fact that it has been observed by Lehmann et al¹ (1987) Miyazaki et

al ¹⁸ (1997) and Oshawa et al ¹⁶ (1992) to be critical in the management of knee hyperextension, and by Lehmann et al ¹ (1987) Corcoran et al ² (1970) Weiss et al ⁶ (2002), and Beckerman et al ⁷ (1996) to be critical in ensuring smooth rollover in stance phase so as not to impede tibial progression. In the opinion of this reviewer, the most important function of an AFO in the management of stroke is to control the alignment of the tibia through the stance phase, as this can help normalise the bending moments generated at the knee and at the hip, thereby influencing swing phase as well as stance. Further work is required in this area.

Implications for further research

A number of questions may be posed in the hope that further research may provide answers

1. What is the optimum timing for orthotic intervention, and would earlier orthotic intervention affect the time required to reach rehabilitation milestones and/or discharge dates?
2. Would the use of AFOs reduce the incidence of contracture?
3. Would the use of ankle-foot orthoses early in rehabilitation encourage early and/or improved weight bearing through the affected limb?
4. To what extent can the use of an ankle-foot orthosis influence the kinetics of the affected hip?

First Author	Year	# of patients	Level of evidence
Lehmann	1987	7	5 (Cross Sectional Survey)
Corcoran	1970	15	5 (Cross Sectional Survey)
Danielsson	2002	10	5 (Cross Sectional Survey)
Franceschini	2001	13	5 (Cross Sectional Survey)
Dacso	1963	10	5 (Cross Sectional Survey)
Weiss	2002	10	5 (Cross Sectional Survey)
Beckerman	1996	60	2b (Randomized Control Trial)
Beach	1999	1	6 (Case Report)
Mueller	1992	1	6 (Case Report)
Diamond	1990	1	6 (Case Report)
Dieli	1997	3	5 (Cross Sectional Survey)
Iwata	2003	17	5 (Cross Sectional Survey)
Mojica	1998	8	5 (Cross Sectional Survey)
Oshawa	1992	39	5 (Cross Sectional Survey)
Burdett	1988	19	5 (Cross Sectional Survey)
Aggett	1999	13	5 (Cross Sectional Survey)
Chen	1999	24	5 (Cross Sectional Survey)
Miyazaki	1997	20	5 (Cross Sectional Survey)
Beckerman	1996	60	2b (Randomized Control Trial)
Johnston	1994	99	5 (Cross Sectional Survey)
Milani	2001	18	5 (Cross Sectional Survey)

Table.1 ranking of papers reviewed

First Author/ Year	(n)	Orthosis	Intervention/Method	Results	Level of evidence
Lehmann (1987)	7	Rigid metal AFO - 5° dorsiflexion vs. Rigid metal AFO - 5° plantarflexion	Measured gait kinetics and kinematics and compared with normal subjects at similar speeds. Compared effects of AFO fixed at 5° dorsiflexion and 5° plantarflexion.	↑ walking velocity (statistically greater increase in dorsiflexed AFO) ↑ step length ↑ gait symmetry Recurvatum controlled (using dorsiflexed AFO)	5
Corcoran (1970)	15	Metal AFO - 10° dorsiflexion vs. Plastic AFO - 10° dorsiflexion	Measured O ₂ consumption at controlled walking speeds using metal and plastic AFO in the same angle of dorsiflexion.	↓ O ₂ consumption ↑ walking velocity No significant difference between AFO types N.B. Hemiparetic gait required 51% (braced) -67% (unbraced) higher energy expenditure than normal subjects at same speed	5
Danielsson (2002) (abstract)	10	Carbon Fibre AFO	Measured O ₂ consumption and heart rate Compared results with/without AFO at self-selected unbraced speed	↓ O ₂ consumption (p<0.05) Heart rate unaffected	5
Franceschini (2001) (abstract)	13	Custom plastic AFO	Tested patients after 1-3 week training programme. Used Perry & Garret walking ability questionnaire and evaluated energy cost of walking using miniature telemetry equipment at comfortable speed	↑ gait functionality (p<0.019) ↓ O ₂ consumption ↑ walking velocity (p<0.01) ↑ gait symmetry ↑ weightbearing	5
Dacco (1963)	10	Not described	Collected expired air in Douglas Bag/portable respirometer during 5-minute walk with and without AFO at comfortable walking speeds	↓ energy expenditure 28.4% (cal/min/kg) using orthosis & training Training accounted for 71.6% of reduction in energy expenditure N.B. Final energy expenditure remained 31% higher than normal subjects	5
Weiss (2002) (abstract)	10	Articulating AFO vs. Solid AFO - 5° dorsiflexion	Compared stride characteristics and gait in patients fitted with articulating AFO and solid AFO using compression-closing footswitches and VICON motion analysis	↓ walking velocity with solid AFO, but increase with articulating AFO ↓ stride length with solid AFO, but increase with articulating AFO ↓ cadence with solid AFO, but increase with articulating AFO (articulating AFO results > unbraced>solid AFO)	5
Beckerman (1996)	60	Solid polypropylene AFO in 5° dorsiflexion vs. "placebo" AFO (hinged AFO/ free sagittal plane motion.	Measured the "ambulation" category of the Sickness Impact Profile (SIP) and walking speed	↑ comfortable and maximum walking speed with SAFO (clinically insignificant) ↓ equinus Varus controlled 44/60 patients complained about fit 50% non-compliance rate	2
Beach (1999) (abstract)	1	Solid AFO vs. TPE AFO	Used VICON to measure kinetics/kinematics/emg. Compared gait with no orthosis/solid polypropylene AFO and thermoplastic elastomer TPE AFO	↑ walking velocity ↑ step length (TPE AFO > SAFO)	6

Mueller (1992)	1	DAFO	Collected foot-loading data using EMED-SF® plantar pressure analysis system Measured Total Foot Force, Total Foot Area and Total Foot Contact time	<ul style="list-style-type: none"> ↑ Total Foot Area in contact with floor ↑ Total Force generated ↓ total stance time ↑ walking velocity ↑ weightbearing (<i>affected leg</i>) 	6
Diamond (1990)	1	DAFO vs. PLS	Used Electrodynegram system to measure gait characteristics at comfortable speed. DAFO vs. PLS vs. barefoot	<ul style="list-style-type: none"> ↑ walking velocity ↑ step length (<i>DAFO > PLS</i>) ↑ gait symmetry (both) ↓ cadence (both) No effect on spasticity 	6
Dieli (1997)	3	DAFO (plantarflexion-stop) vs. PLS	Used footswitch stride analysis to compare gait characteristics of patients using DAFO vs. PLS vs. barefoot	<ul style="list-style-type: none"> ↑ walking speed ↑ step length ↑ gait symmetry (<i>DAFO > PLS > barefoot</i>) ↑ cadence (<i>DAFO > barefoot > PLS</i>) ↑ weightbearing ↓ equinus (<i>DAFO > PLS</i>) Varus controlled (<i>DAFO</i>) no effect on spasticity 	5
Iwata (2003)	17	PLS (modified with inhibitor bar)	Tested effect of adding inhibitor bar to PLS on gait of patients with Tonic Toe Flexion Reflex	<ul style="list-style-type: none"> ↑ walking velocity ($p=0.0045$) ↑ cadence ($p=0.0056$) ↑ step length ($p=0.398$) (<i>TFRR group only</i>) 	5
Mojica (1998)	8	Plastic AFO	Measured body sway, total sway of centre of foot pressure, and maximum walking speed with and without AFO	<ul style="list-style-type: none"> ↑ step length ↑ cadence ↑ weightbearing (<i>affected leg</i>) ↓ body sway 	5
Oshawa (1992)	39	FAFO (II)	Describes new model of AFO to control equinus and recurvatum and reports observations on 39 patients	<ul style="list-style-type: none"> Varus corrected Equinus corrected Recurvatum controlled (<i>21/23 patients</i>) 	5
	3	Yukono AFO Hemispiral Shoehorn FAFO (II)	Gait of 3 patients analysed using 4 different AFOs	<ul style="list-style-type: none"> FAFO (II) controlled recurvatum best (<i>10 degree dorsiflexed alignment</i>) ↑ gait speed (best with FAFO (II)) ↑ step length (best with FAFO (II)) ↓ hamstring/ gastrocnemius activity ↑ quadriceps activity (<i>best FAFO (II))</i> 	

Burdett (1988)	19	Air Stirrup™ vs. unbraced	Hip, knee and ankle angles, inversion and eversion of calcaneus and time-distance gait characteristics measured from videotaped trials and footprint analysis.	walking velocity unchanged (AS) ↑ step length (AFO/AS>unbraced) ↓ equinus (AFO>AS>unbraced) ↓ varus (AS vs. unbraced)	5
	11	Air Stirrup™ vs. unbraced vs. AFO (metal jointed or plastic at 90° or 5° dorsiflexed)			
Aggett (1999) (abstract)	13	Air Stirrup™	Measured temporal/spatial gait parameters, joint angles GRF using CODA and force plate, before and after provision of Air Stirrup™.	walking velocity unchanged step length unchanged ↓ equinus (p= 0.016) ↓ varus (p=0.009) temporal/spatial gait parameters unchanged	5
Chen (1999)	24	Anterior AFO	Measured postural sway index, postural (weightbearing) symmetry, maximum AP and lateral balance range	↑ weightbearing (affected leg) ↑ lateral weight shifting	5
iyazaki (1997)	20	Experimental AFO	Investigated the effect of dorsiflexion/plantarflexion rigidity and initial angle of AFO on moment generated by ankle musculature during gait using experimental AFO.	Recurvatum controlled when AFO dorsiflexed 7 degrees	5
Beckerman (1996)	60	Solid polypropylene AFO in 5° dorsiflexion vs. "placebo" AFO (hinged AFO/free sagittal plane motion)	Measured changes in spasticity, muscle tone, ankle clonus, Achilles tendon reflex, ankle PROM, motor function of leg and balance at 6 and 15 weeks after randomisation.	No AFO effect on spasticity, muscle tone, Achilles tendon hyperexcitability, or ankle clonus 28/60 non-compliance	2
Johnston (1994) (abstract)	99	Not described	Functional Independence Measure, gait speed, patient attitudes assessed during hospital stay. Device usage assessed 3 months after discharge by telephone survey.	26.3% did not use Slower, less safe/more disabled (FIM)/ those with greater proprioceptive loss used more)	5
Milani (2001) (abstract)	18	Prefabricated AFO vs. Custom Solid AFO	Compared patient satisfaction with, and use of, prefabricated vs. custom fabricated AFO	41.7% prefabricated group comfortable vs. 88.9% custom group 58.3% prefabricated group satisfied with gait vs. 100% custom group.	5

Table 2. Summary of Evidence

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ARTICULATED ANKLE FOOT ORTHOSIS DESIGNS (R3)

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INTRODUCTION

A major goal of rehabilitation after stroke is retraining mobility. Although there is much variation, individuals post stroke display certain similarities in their ability to walk. First, velocity is usually decreased as a result of some combination of smaller step length and lower cadence¹. At slower walking speeds, increased muscle activation is necessary to advance the leg in swing due to decreased momentum. Additionally, difficulty with muscle activation also is common post stroke². Second, walking is asymmetrical, usually with a lessened ability to shift weight onto the hemiplegic leg^{3,4}.

Initially the hemiplegic foot and ankle are often flaccid, exhibiting a passive foot drop with difficulty clearing the toes during swing. With recovery, this usually progresses to a more dynamic foot that still postures during swing into a plantarflexed/supinated position. This continues to present the individual post stroke with difficulty clearing the toes, especially when combined with the decreased swing hip and knee flexion that also often accompany this gait deviation⁵. Over time, the heel cord frequently becomes tight⁶⁻⁸ resulting in additional compensations. At initial contact, the supinated foot often lands on the lateral border and in relative PF⁵ resulting in an unstable base of support at the beginning of stance phase. In some individuals, this supinated position remains throughout stance, but in many, the foot then collapses into an excessively pronated position as the body moves forward over the foot⁹. These abnormal foot positions during stance in turn affects body segments above the ankle⁵. Proximally, it is often difficult to smoothly transition the center of mass over the base of support during the gait cycle. In other words, the individual post stroke has difficulty keeping the upper body aligned over the pelvis, and the pelvis aligned over the leg and foot. This, along with difficulty smoothly and reciprocally activating knee and hip muscles, can lead to knee instability³⁻⁵.

Ankle foot orthoses (AFOs) are hypothesized to improve hemiplegic gait in several key ways. First, most braces provide medial/lateral stability at the foot and ankle, preventing excessive destabilizing supination. Certain designs also prevent excessive pronation when the foot collapses with weight bearing. Second, bracing can prevent excessive plantarflexion, assisting in normalizing both toe clearance in swing as well as forward progression in stance. Finally, the ankle position of the brace can be used to influence the position and stability of the knee.¹⁰

One design of AFO commonly used to improve walking ability in individuals post stroke is an articulated ankle foot orthosis. Articulation is defined as having a hinge or pivot connection¹¹. Articulated ankle foot orthoses contain some form of hinge joint external to the talocrural joint. This category includes traditional metal double upright braces as well as newer thermoplastic designs containing metal

and plastic hinge joints^{5,10,12-19}. Many types and settings of hinges are available, allowing free ankle dorsiflexion (DF) and plantarflexion (PF) movement, stopping movement in a specific direction and through specific ranges, and/or assisting motion with some form of spring mechanism. However research evidence indicating when to use of an articulated AFO, as well as when certain designs or features are clinically most important, is limited¹⁹⁻²².

The purpose of this key review is twofold. First, it will examine and summarize the research related to articulated AFO designs, rating the level of evidence and establishing a grade of recommendation for the research^{23, 24}. Of particular interest is whether articulated designs perform better or differently than non-articulated designs, as well as whether certain features or types of articulated bracing result in superior performance. As the stroke population represents a heterogeneous group, it is expected that certain designs and/or features may be indicated according to the specific impairments of a given individual. Second, this review will identify gaps in the available research evidence, and from this information, areas for further research will be discussed.

METHODS

A literature search was completed using Recal, Medline, and Cinahl, as well as through review of cited references from appropriate articles. Articles selected for review met the following criteria:

- Research was related to stroke; either the majority of the research subjects were individuals with stroke, or the research question was related directly to orthotic interventions for individuals with stroke.
- The intervention investigated some question related to articulated AFOs; articulated AFOs were clearly identified in the study and investigated as a separate category of bracing intervention from other types of orthotic devices.
- Some form of quantitative outcome measurement, including at least descriptive statistical analysis, was presented in the article.
- The study was published in a peer-reviewed journal in English.

In addition, peer reviewed abstracts from 2002 and 2003 Gait and Clinical Movement Analysis Society's annual meeting were reviewed and included if they met the above criteria, as presentations at this meeting frequently focus on clinical bracing questions and reflect current research that is not yet in publication. These are clearly categorized as "abstracts" in the *Author/Publication Date* column of the individual article summaries.

Articles were categorized into one of three general groups reflecting the type of articulated AFO: Double adjustable articulated AFOs (includes single upright Valens caliper);

standard articulated AFO (thermoplastic AFO with some form of hinge joint), and ground reaction AFO (anterior shin piece, designed to affect sagittal knee position through positioning of ankle joint). The one systematic review was placed in multiple categories, reflecting its review of studies in several bracing groups.

In addition, each of these bracing classifications was then subcategorized according to the general type of outcome measurement: mechanical testing, motion analysis testing, or clinical measurement. In cases where overlap between testing methods existed, the study was placed in the category in which the majority of measurement occurred. A brief summary of evidence is provided after each group of studies.

Each individual study is summarized by category in table format to allow easy comparisons. The summarized features of each article are organized as follows:

- 1) Number of subjects (Ss) and characterization of the subjects *as available*:
 - a) Diagnosis
 - b) Date of onset/time post cerebrovascular accident (CVA)
 - c) Motor control/strength/tone (Brunnstrom stage of motor recovery²⁵, clonus, modified Ashworth scale²⁶, deep tendon reflexes, etc.)
 - d) Ankle DF PROM/ PF contracture,
 - e) Level of independence walking
- 2) Study design
 - a) Type of study (cross-over, case series, randomized clinical trial, systematic review, etc.)
 - b) Any randomization of order
 - c) Any blinding of conditions, evaluation
 - d) Time wearing AFO(s) before testing (if not noted, then all conditions were tested on the same day/session without prior practice using a given brace)
- 3) Bracing styles that are compared in the study
- 4) Outcome measurement in the following categories: Kinematics, kinetics, EMG, energy consumption, stride analysis, clinical measures, subjective opinion
- 5) Results and conclusions as related to the purpose of this review (some studies also include information about other questions, such as hemiplegic gait characterization²⁷, or a non-orthotic treatment intervention²⁸; these unrelated results are *not* included in this review)
- 6) Level of evidence and grade of the study^{23, 24}

RESULTS

Sixteen articles and two abstracts were identified meeting the review criteria. Each of these studies is summarized below in Tables 1-6. There were no articles found pertaining to the ground reaction articulated AFO category (Table 6). Additional related articles were not included in this review for the following reasons. First, some did not clearly categorize articulated AFOs as a separate category from non-articulated braces²⁹ or did not clearly identify the type of AFO (articulated or non-articulated) in the description of the braces tested³⁰⁻³³. Second, a number of articles about design features and prescription of orthoses, specifically

related to stroke^{13, 34, 35} as well as for multiple diagnostic groups^{10, 12, 36-39}, serve as good reviews of the literature but do not complete that necessary statistical analysis to qualify as a systematic review or meta-analysis^{23, 24}. Thus, while these articles form the basis of expert opinion and best current clinical practice^{23, 24}, they were not included in this review due to lack of quantitative outcome measurement. Finally, several studies have been completed examining articulated bracing designs with children with spastic diplegia⁴⁰ and hemiplegia cerebral palsy^{41, 42}. Hemiplegic cerebral palsy in particular presents very similarly to adult hemiplegia, although caution in applying pediatric bracing research conclusions directly to an adult population must be observed due to differing weight/size effects on AFO stiffness characteristics as well as differences in abnormal muscle tone between the two groups⁴³.

Of the 18 reviewed articles and abstracts, 5 were case series (level VI evidence/Grade C), 11 were case control studies (level IV evidence/Grade B), one was a randomized controlled trial with non-definitive results (level II b evidence/Grade B), and one was a systematic review (level I evidence/Grade A). The majority of the studies, 16 out of 18, utilized a cross-over design, in which each subject serves as his own control and receives all intervention and control bracing conditions²³. This repeated measures design decreases the inter-individual variance and is appropriate for use with the heterogeneous stroke population⁴⁴, especially in clinical bracing research where it is difficult to fund studies with large numbers of subjects.

Although Grade A evidence about articulated AFO designs is sparse, the reader must be cautioned to remember that in the evidence based practice model, Grade C research forms the basis to develop and complete Grade B studies, and grade B studies form the basis to design Grade A investigations. Without the underlying information provided by case series and case control studies, randomized clinical trials cannot be developed⁴⁵. Equally important to recognize is the need for research exploring not only whether or not a bracing intervention improves gait, but the underlying reasons for that improvement⁴⁶. Kinematic and stride analysis data were collected in all but one of the studies, helping to elucidate *what* changed with different bracing interventions. Significantly, however, in 11 of the 18 reviewed studies, kinetic and EMG data also were collected, allowing a better understanding of *why* changes occur.

Of the 17 individual research studies reviewed (not including the systematic review), 7 compared articulated to non-articulated designs, and 10 compared different features possible within articulating designs. Four of the studies only compared walking with an articulated brace to walking using no brace. Of the 7 articulated to non-articulated comparison studies, one was a descriptive study without human subjects, 4 found no significant differences between the two types of braces, while 2 found that the articulated AFO resulted in the best gait.

DISCUSSION

Despite common prescription of articulated AFOs post stroke, there has been little research examining this in-

intervention. The available research is often nonsystematic as well as inconclusive, in part due to the heterogeneous nature of the stroke population. This key review raises three questions that can serve to guide future research about orthotic use with stroke patients. First, what do we expect to change as a result of a bracing intervention? Are there critical outcomes that require measurement in this research? Second, who should we study? Since the stroke population presents with heterogeneous group of impairments, what are the critical differences between individuals that need to be controlled for in this research? Finally, how should we study this intervention? Can we design our studies more systematically? Addressing what we expect to change and controlling who we study will help with this problem.

What outcome measurements are important in examining the effectiveness of AFOs post stroke? Disablement models stress that the goal of rehabilitation post stroke is to improve function and the ability to fulfill personal and societal roles in life^{3, 47}, and orthotic prescription should assist in the achievement this goal. While it is commonly assumed that AFOs improve ambulation in individuals post stroke, what measures assess change in functional ambulation? For example, just because a particular brace results in a more normal gait pattern, such as better heel strike, does not necessarily mean that walking function has improved. And should not functional mobility be broadened to include additional activities affected by the use of an AFO, such as mobility on stairs, inclines, out of doors, in transitioning from sit to stand, and during standing activities requiring balance, as well as by the endurance requirements necessary to complete these activities, as suggested by Patla and Shumway-Cook⁴⁸? Of the reviewed studies, only Corcoran's⁴⁹ work examined energy consumption related to use of an AFO and ambulation on anything other than level surfaces.

How can functional changes in ambulation on level surfaces be measured most effectively? The reviewed studies used a wide range of measurement categories: stride analysis, kinematic & kinetic measurement, EMG, energy consumption, other clinical measures such as the Functional Ambulation Profile⁵⁰ and the Sickness Impact Profile⁵¹, and subjective questionnaires. One valid and reliable measure⁵², however, used in 14 out of the 16 reviewed clinical bracing studies was gait velocity. Richards and colleagues^{1, 4, 52, 53} grouped gait velocity in stroke patients into functional categories of slow (12-20cm/s; 23% mean gait velocity), intermediate (28-37cm/s; 48% mean gait velocity), and fast (55-65cm/s; 88% mean gait velocity) walkers. The intermediate and fast walkers can walk independently, but the slow walkers need variable amounts of assistance. Velocity of gait has been correlated to functional performance; individuals who ambulate at less than 30% of normal do not become community ambulators⁵⁴. Kinetic and EMG data also have been correlated with gait velocity¹, as have commonly used clinical stroke measures such as strength⁵⁵, Fugl-Meyer leg scores⁵⁶, the Berg balance test,¹ and the Barthel Index¹. While the Berg, Fugl-Meyer and Barthel Index have been shown to be sensitive to change in the early phases of recovery post stroke, and are thus appropriate to use during

this time period⁵², these measures become less sensitive to change in later recovery. Therefore it is suggested that gait velocity be used as a functional measure during later time periods because it remains sensitive to change^{1, 52}. However the Berg, Fugl-Meyer and Barthel Index are more sensitive to levels of change in early stroke patients than gait velocity¹, and should be used to discriminate between different levels of functional ambulation within the dependent, slow walker group⁵².

In summary, it is recommended that future clinical research into efficacy of orthotic use post stroke be expanded to examine broader categories of functional mobility in conjunction with assessment of ambulation on level surfaces. Measurement of gait velocity should continue to be used as an indication of walking function on level surfaces, but in low-level ambulators, velocity should be coupled with some additional clinical measure of walking ability such as the Barthel Index. Whether or not mobility function changes as a result of an orthotic intervention is a crucial question that must *always* be addressed. This recommendation, however, does not imply that evaluation of changes in other domains, such as muscle function (EMG) or joint moments and powers (kinetics), should be discontinued. Assessment of these areas allows us to better understand *why* mobility function is changing, and is essential in developing a better understanding of the intervention strategies being utilized in clinical practice. For example, three power bursts in late stance at the ankle (A2), knee (K3), and hip (H3) provide the forward propulsive force necessary to generate increasing walking speed⁵⁷ and are deficient to varying degrees in stroke patients⁵⁸. A research study using gait velocity as an outcome measure of *how* mobility function changes might also examine differences in these power bursts in order to elucidate *why* a particular bracing design is improving mobility function.

A second question raised by this key review relates to the heterogeneous nature of the stroke population. Characterization of the subjects in the reviewed studies varied in both depth of description as well as breadth of the different impairments present. It is probable that some of the differing results occurred because of varying reported and unreported impairments amongst subjects, both within and between studies. As well as allowing comparison within a more homogeneous group, these factors also often form the basis of outcome measurement about the clinical effect of an orthotic intervention. The following areas of subject characterization probably affect study outcomes:

- Acute vs. chronic (time post CVA)
- Initial walking ability (classification into slow, intermediate, or fast walkers, with further sub classification by clinical measure of the slow walker categories as noted previously)
- PROM at the ankle joint (heel cord tightness)
- Motor control
 - Spasticity/flaccidity (as differentiated from local changes in muscle properties reflected by loss in ankle PROM)
 - Muscle hyperreflexia

- Muscle strength and power
- Muscle activation patterns
- Accessible movement patterns and strategies (for example, Brunnstrom stages of recovery²⁵, reactive balance strategies²)
- Compensatory movement patterns (for example, excessive coactivation^{2, 59})

Although some variation is reported in the time frame of recovery post stroke as well as what is designated its acute versus chronic phase⁵², it is recognized that bracing requirements change across these periods of time¹³. In the 14 reviewed articles examining stroke patients, 4 did not report the time post stroke for the research subjects. Of the remaining 10 studies, 6 examined a mix of individuals in both acute and chronic phases of recovery. It is recommended that future studies control for the chronicity of the stroke.

Likewise, 7 of the 14 studies did not report on the initial level of ambulatory ability of the subjects, although this can be inferred in the faster ambulators by their walking speed. It is probable that bracing interventions affect stroke patients differently depending on their level of mobility function and it is therefore recommended that future research control for initial ambulatory ability since this is an important outcome measure.

In articulated AFO designs, the availability of PROM at the talocrural joint is a crucial factor.

While 9 of the 14 clinical studies noted this factor in their description of subjects, what constituted “no ankle PF contracture” was unclear to the reviewers in 8 of the articles. Weiss⁶⁰ and Eberly’s⁶¹ abstracts point out the critical importance of this factor when evaluating the effectiveness of articulated AFOs. However, since loss of heel cord PROM is a common problem in chronic stroke^{7, 8} and accurate measurement of ankle PF PROM is complex⁶²⁻⁶⁴ the specific measurement method must be accurately reported in order to better understand the impact of this factor on bracing interventions.

To further complicate this issue, the etiology of decreased ankle dorsiflexion after stroke remains controversial and is closely interrelated with the remaining motor control impairments being discussed, each described to varying degrees in the reviewed studies. While spasticity, or dynamic muscle hyperreflexia, over time, probably does lead to muscle shortening and decreased PROM, it is not a straight forward cause-effect relationship^{6, 65} because spasticity itself is a clinical syndrome that arises from multiple underlying types of motor control disorders^{65, 66}. O’Dwyer and colleagues⁶ suggest a model where a central nervous system lesion may cause increased “stiffness” via two distinct mechanisms, or some combination of the two, depending on the underlying movement disorder. First is the commonly accepted avenue of reflex hyperexcitability (spasticity), as well as dynamic muscle over activity, usually not consciously controlled or only poorly controlled by the patient. Second is through altered muscle function that in turn leads to altered local passive mechanical properties in the muscle. Since it is difficult to separate these dynamic and passive elements on clinical examination, what recom-

mendations can be made for assessing this complex area of motor control dysfunction post stroke? As previously mentioned, accurate measurement of ankle PROM, along with characterization of active range of motion at this joint is necessary. Reporting Brunnstrom stages of recovery²⁵ is helpful, as seen in 5 of the 14 clinical reports, along with quantification of spasticity using of the modified Ashworth scale²⁶, measurement of clonus and Achilles tendon tap responses utilized by 4 of the 14 articles. However, at present, use of the sophisticated EMG and kinetic technology available in a motion analysis laboratory is vital to developing a better understanding of how these factors relate to the use of orthotic interventions post stroke. This is necessary, for example, to answer the question in Leung and Mosley’s systematic review about whether muscle function is affected by long-term use of an AFO. This review found only 4 studies that examined this issue. One hypothetical reason to begin using an articulated AFO acutely before development of heel cord tightness, besides preventing the development of PF contracture as well as providing the biomechanical mobility necessary for more normal movement, is to provide the opportunity for muscle reeducation and functional recovery. Theoretically this may prevent the disuse atrophy often seen by the authors in chronic stroke patients using non-articulated AFOs for extended periods of time. While this issue has been examined to some degree in normal subjects and individuals with lower motor neuron lesions⁶⁷⁻⁶⁹, it has received minimal research attention in the stroke population. In examining this question, it is essential to begin with a group of subjects who present with similar PROM as well as levels of motor control dysfunction, since these areas are so interrelated. Changes in these areas can then be assessed over time in relation to the use of different AFO designs.

The final question raised by this review relates to the lack of systematic study design in the current literature. First, several studies could not even be evaluated for inclusion in this review because of inadequate descriptions of the study orthoses³⁰⁻³³. Franceschini and colleague’s³³ recent article, for example, did not clearly describe the “Seattle” orthosis being evaluated in the study. Therefore a recommendation in being made for the development of more consistent nomenclature for bracing categories, as well as inclusion of better descriptions of AFO designs in the research literature.

More important is the need for systematic research design. For example, it is not uncommon to see an article in the research literature comparing a non-articulated AFO, an articulated AFO, and/or a supramalleolar level dynamic AFO, and one or more of the braces may have “tone-inhibiting” or some other special feature^{42, 49, 70-72}. When comparing a supramalleolar level brace with “tone-inhibiting” features to a standard below knee height brace without “tone-inhibiting” features, how can the investigator speculate on possible reasons for study findings? The comparison braces are different heights, have different foot bed contouring, and are made of plastic with differing rigidity. In order to begin answering some of the many questions about efficacy of different designs and design features, a more systematic

approach must be taken. For example, Brunner and colleagues⁴¹ did a single mold and fabricated 2 identical AFOs from the mold. They then cut a wedge out of the ankle area of one of the AFOs and inserted a spring type hinge. By doing this, there was only one factor changed between the 2 comparison braces. We recommend examination of well-defined populations of stroke patients using a single bracing style that can be systematically varied in the following types of ways:

- Height of AFO calf piece
- Initial angle of ankle DF in solid ankle brace
- PF stop angle in a brace with free DF
- DF springs with increasing wire diameter/spring constants
- Foot bed contouring or no contouring
- Full length foot bed or shorter foot bed

In all cases, only one factor at a time should be varied systematically in order to understand how changing this factor affects mobility function. Without this analytical approach, we will continue to compare apples to oranges in research and it will be difficult to develop evidence-based prescriptive criteria for the use of AFOs post stroke.

CONCLUSIONS

In this review of articulated AFOs, it remains unclear whether or not articulated designs are effective in improving ambulation post stroke. They *may* be beneficial in individuals post stroke with certain types of impairments. The research does suggest that certain features are preferable. However, a wide variety of different features were assessed by various investigators, and no consistent pattern or preferred design was found across different research studies.

	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Miyazaki et al 1993 ²¹	8 normals simulating hemiplegic gait and walking speed	Cross-over between EIAFO & plastic foot piece as well as between internally instrumented AFO and external measurement system	1. Experimental instrumented AFO (EIAFO) (plastic foot piece attached to double metal uprights with bilateral ankle joints and posterior cuff belt at top) without springs (free DF/PF); 2. With plastic foot piece of EIAFO only	Kinetics: Continuous ankle joint moment measured through the internally instrumented EIAFO as well as through a sensitive external motion analysis system consisting of force plate/camera	<ul style="list-style-type: none"> The measurement accuracy within the internal system of the EIAFO compares well to that of other external gait analysis systems 	IV B
Yamamoto et al 1993 ⁷³	2 CVA; 7 & 13 months post CVA; Brunnstrom LE stage III; using shoehorn type AFO at time of study; ambulation independence level not reported	Cross-over design; Case series with statistical analysis	1. Experimental instrumented AFO (EIAFO) (plastic foot piece attached to double metal uprights with bilateral ankle joints and posterior cuff belt at top) with spring #1 providing DF/PF assists; 2. EIAFO with spring #2 3. EIAFO with spring #3 4. With plastic foot piece of EIAFO only	Kinetics: Ankle joint floor reaction moment and muscle moment, AFO moment Kinematics: Ankle and knee sagittal motion EMG: Ankle DF and PF Stride analysis: Step length and velocity	<ul style="list-style-type: none"> EIAFO was heavy and may not adequately simulate a plastic AFO An optimum spring setting could be determined for each subject in about 90 minutes Ankle PF muscle moment varied considerably depending on AFO setting; AFO only provided a very minimal PF corrective moment; ↑ ankle PF muscle moment may have been due to medial-lateral stabilization provided by AFO or due to dynamic matching between mechanical & human factors; 	VI C
Yamamoto et al 1993 ⁷⁴	15 CVA; 4-21 months (except one 78 months) post CVA; largely Brunnstrom LE stages 3-4 (except one 2-3, one 4-5); no severe hypertonicity or ankle contracture; 13/15 using shoehorn type AFO at time of study; ambulation independence level not reported	Cross-over design	1. Experimental instrumented AFO (EIAFO) (plastic foot piece attached to double metal uprights with bilateral ankle joints and posterior cuff belt at top) without springs (free DF/PF); 2. EIAFO with PF stop; 3. EIAFO with a combination of 2-5 springs; 4. No AFO	Kinetics: ankle joint moments; Kinematics: knee and ankle sagittal plane motion; Stride analysis: total cycle, stance, swing, double/single support, heel contact to forefoot contact time; Subjective opinion of subjects about best AFO	<ul style="list-style-type: none"> Subject's opinions about "best" AFO setting correlated fairly well with quantitative gait data; "Best" AFO setting according to gait data did not necessarily correlate with spring setting generating maximal DF corrective moment or with more normal knee extension; Significant differences in gait parameters found according to AFO setting, with the "best" setting correlating with <ul style="list-style-type: none"> lowest cycle time/↑ gait velocity (lowest affected side swing phase time and unaffected side double support time), a decrease in excessive knee extension at then end of stance phase, a more normal PF moment 	IV B

	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Miyazaki et al 1997 ²⁰	20 CVA; 3-21 months post CVA;Brunnstrom LE stage III-IV (one stage V); all with PF spasticity to varying degrees; ambulation independence level not reported	Cross-over design	1.Experimental instrumented AFO (EIAFO) (plastic foot piece attached to double metal uprights with bilateral ankle joints and posterior cuff belt at top) with ant/post springs in first collection session (9 subjects) and just anterior springs in second collection session (11 subjects) set at neutral; 2.EIFOA with spring(s) set in DF; 3.EIAFO with no springs/ stops; 4.EIAFO with 90° PF stop 5. No AFO	Kinetics: ankle joint moment floor reaction, orthotic, and active ankle moments); Kinematics: Knee and ankle joint sagittal plane motion; EMG: Tibialis anterior, gastrocnemius; Stride analysis: foot contact timing	•Orthosis (anterior spring) assisted DF at initial contact; •PF moment later in stance largely generated by plantarflexor muscles, therefore AFOs contribute only minimally to the overall PF moment; •Slight assist to PF moment by orthosis (posterior spring) contributed to difficulty clearing toes) therefore discontinued in 2 nd test session; •In most cases (16 out of 20), the highest active ankle PF moment corresponded both to the subject's and investigator's judgment of "best" gait performance; •Statistically, 11/20 subjects showed a significant change in active ankle moment depending on rigidity and initial angle of AFO setting, therefore some form of dynamic matching of AFO characteristics to the individual patient is recommended	IV B
Yamamoto et al 1997 ⁵	33 CVA; regularly used a plastic AFO at time of study; no additional description of subjects; ambulation independence level not reported	Cross-over design; Case series with descriptive statistics only, no group analysis	1.Experimental instrumented AFO (EIAFO) (plastic foot piece attached to double metal uprights with bilateral ankle joints and posterior cuff belt at top) with variable combinations of 4 possible anterior (DF assist) springs providing increasingly greater DF assist moments a.1.0 mm/0.06 kgf/mm b.1.2 mm/0.16 kgf/mm c.1.4 mm/0.37 kgf/mm d.1.6 mm/0.77 kgf/mm 2.EIAFO also with variable initial DF joint angle from 0-10° 3.4 subjects tested with posterior PF springs also	Kinetics: Ankle joint moments; Kinematics: Knee & ankle sagittal plane motion; Stride analysis: Velocity, cycle events	•Orthotic assisted PF moment (posterior springs) made subjects feel uncomfortable during walking; •DF during mid- to late stance was decreased while PF increased during swing when using the PF moment assist (posterior springs); •In approximately 30 minutes, could determine best spring combination from 4 choices, as well as best setting for initial angle of ankle in brace; •Most normal walking velocity and knee position correlated with subject's opinion of best spring setting; •No relationship between chosen best spring setting and chosen initial ankle angle in brace; •If forward thrust/unstable knee → ↓ DF assist moment, set initial ankle angle at neutral; •If ↑ knee flex/ankle DF at foot contact → set initial ankle angle at neutral; •If knee hyperextension mid to late stance → ↑ DF assist moment; •If excessive elongation of push off → set initial ankle angle in DF; •If external rotation/excessive hip flexion late stance → ↓ DF assist moment; •If insufficient toe clearance during swing → set initial ankle angle in DF	VI C

Table 1: Double Adjustable Articulated AFO: Mechanical Testing

Authors & publication date	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Lehmann et al 1987 ²⁷	7 CVA + 7 age/sex/weight/ height matched normals/ 3-13 years post CVA; only 5° DF in 3/7 Ss; no active isolated DF in any of Ss; ambulation independence level not reported	Cross-over design	1. Double metal upright AFO fixed in 5° DF; 2. Double metal upright AFO set in 5° PF; 3. Shoes only	Kinematics: LE 3-dimensional Kinetics: knee flexion moment; Stride analysis: velocity, step length, affected heel strike, midstance, & push off duration	<ul style="list-style-type: none"> • Walking speed significantly ↑ no brace to DF AFO & PF AFO to DF AFO (DF AFO most normal speed); • Heel strike duration significantly ↑ no brace to DF AFO and PF AFO to DF AFO (Most normal in DF AFO); • Midstance duration significantly ↓ no brace to DF AFO and no brace to PF AFO (most normal PF AFO); • Push off duration significantly ↑ no brace to DF AFO and PF AFO to DF AFO (most normal DF AFO); • Knee flexion moment midstance ↑ no brace to DF AFO and PF AFO to DF AFO (most normal DF AFO) 	IV B
Corcoran et al 1970 ⁴⁹	15 CVA + 32 normals (4M,4 F each decade from 20 to 60 years); 5 to 79 months + 1 14 year post CVA; either no PF contracture (10-25° DF with knee extension, 4/15 with only 10° DF) OR no PF spasticity (3/15 with sustained clonus, 7/15 with 4+ Achilles tendon reflex); independent ambulators	Cross-over design with random order of conditions; Used each brace at least one week before testing	1.Double metal upright AFO fixed in 10° DF; 2.Solid plastic custom AFO; 3.No brace	Energy expenditure: O ₂ consumption; Stride analysis: velocity level surfaces and stairs	<ul style="list-style-type: none"> • Walking speed level surfaces and stairs significantly faster in both braces as compared to no brace (but no difference between braces); • O₂ consumption at comfortable walking speed significantly ↑ all hemi conditions as compared to normals (most ↑ no brace condition) and ↑ in no brace condition as compared to brace conditions (most normal O₂ consumption in plastic AFO condition) 	IV B

Hesse et al 1999 ⁷⁶	20 CVA; 1 brain tumor with hemiparesis; 1.5 to 16 months post injury; marked PF spasticity with modified Ashworth score for ankle PF 3-5 range & clonus during barefoot walking in 7/20; no ankle contractures (plantigrade posture after 10 min. of standing); 3/21 with neglect; ambulated 20 ft. barefoot without physical assist	Cross-over design; Used Valens caliper < 1 week before testing	1. Valens caliper (1-bar rigid AFO with medial metal upright, posterior calf piece, T strap, attached to shoe, PF stop at 10° PF, spring assist to neutral; neutral DF stop 2. Barefoot	Stride analysis: velocity, cadence, stride length, onset/duration stance/swing, double support Kinematics: ankle DF Kinetics: ground reaction forces at toe-off & heel-on EMG: bilateral tibialis anterior, medial gastrocnemius, vastus lateralis, & gluteus medius	In brace as compared to barefoot: <ul style="list-style-type: none"> • ↑ single-stance time affected side; • ↑ swing symmetry; • ↑ pivoting over stationary paretic foot in stance; • ↑ DF excursion during stance & ↓ PF excursion during swing; • ↑ vastus lateralis activity; • ↓ anterior tibialis activity, which may lead to disuse atrophy & long-term dependence on orthosis • No difference in gait velocity between conditions 	IV B
Leung & Mosely 2003 ¹⁹	CVA; Variable characteristics	Systematic review; Data on velocity, stride length, & cadence, (most common parameters), converted to standardized units with a 95% confidence interval allowing comparison & clinical interpretation between studies	a. No differentiation in summary between articulated and non-articulated design; b. Appendix individually summarizes each article and differentiates between articulated and non-articulated designs	Kinematics; Kinetics; EMG; Stride analysis; Clinical measures; Subjective opinion	<ul style="list-style-type: none"> • AFOs <i>may</i> improve walking speed, improve gait pattern, and improve energy efficiency of gait; • AFO use <i>may</i> reduce active ankle DF muscle activity, but the long-term effect is unclear; • AFO use <i>may</i> also effect ankle PF muscle activity, depending on the biomechanical features of the orthosis; • Less than 50% of the studies examined subject satisfaction/compliance issues with AFOs, and these authors found that it is variable, with most individuals viewing function as more important than appearance; • Only one study examined functional impact and energy expenditure related to AFO use in this population 	I A

Summary of Evidence

This group of studies did not assist in clarifying any differences between articulated and non-articulated designs, or within the varied articulated design categories except to show that a brace set in 5° DF was generally more effective in improving gait than one set in 5° PF²⁷. More normal gait velocity^{27, 49} and gait parameters^{27, 76} were found in 2 out of 3 of the Grade B studies. Corcoran and colleagues⁴⁹ found that energy efficiency improved with use of a solid or articulated AFO as compared to no brace (but no difference between braced) in the only reviewed study examining this important area. Hesse and colleagues⁷⁶, interestingly, found improved quadriceps activity, but decreased tibialis anterior activity in the braced as compared to barefoot condition, and suggested that long-term use of a brace might lead to disuse atrophy. Leung & Mosley's systematic review¹⁹ supports that bracing *may* lead to all of the changes noted in the Grade B studies, but that more research is needed to confirm these conclusions.

Table 2: Double Adjustable Articulated AFO: Motion Analysis Testing

Authors & publication date	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Hesse et al 1996 ⁷⁷	16 CVA, 3 brain tumor with hemiparesis; 1.5-16 months post injury; marked PF spasticity, modified Ashworth score for ankle PF 3-5 range; no ankle contractures (plantigrade posture after 10 min. of standing); 3/19 with neglect; ambulated 20 ft. barefoot without physical assist	Cross-over design; Used Valens caliper < 1 week before testing	1. Valens caliper (1-bar rigid AFO with medial metal upright, posterior calf piece, T strap, attached to shoe, PF stop at 10° PF, spring assist to neutral; neutral DF stop 2. Barefoot; 3. Shoes only	Clinical measure: Rivermead Motor Assessment items # 6 & 7 assessing weight bearing activities on affected LE; Stride analysis: velocity, stride length, cadence, double stance, trajectory of force point of action under foot (% of foot length); Kinetics: qualitative pattern of vertical force diagram; Subjective opinion of subjects	<ul style="list-style-type: none"> Improved performance on Rivermead test items (but no statistical analysis); Significant improvement velocity, cadence, & stride length between all 3 conditions (barefoot to shoes & shoes to AFO), improved heel strike in AFO, more normal trajectory of force point of action & qualitative pattern of vertical forces in AFO; All subjects felt they could walk better with AFO although some thought it was too heavy or did not like its appearance 	IV B
<p>Summary of Evidence</p> <p>Again, this level IV study did not assist in clarifying any differences between articulated and non-articulated designs, or within the varied articulated design categories. Similar improvements in gait velocity and parameters to those found in the "Double Adjustable Articulated AFO: Motion Analysis Testing" category were observed between barefoot & AFO, and shoes and AFO conditions. This study also examined the transfer of weight under the foot and found significant normalization with bracing. It collected information about how the subjects felt about the brace: all subjects felt they walked better with the AFO, although some felt it was heavy and did not like its appearance.</p>						

Table 3: Double Adjustable Articulated AFO: Clinical Measurement

Authors & publication date	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Singerman et al 1999 ¹⁸	No human testing; mechanical testing only (AFO mounted on surrogate shank in mechanical testing frame with proximal strap + bolt and distal fixation similar to a shoe)	Cross-over design; Descriptive statistics only	<ol style="list-style-type: none"> 1. Solid polypropylene AFO (2 versions with differing trim lines); 2. Flexible hinge polypropylene AFO with PF stop, free DF (posterior spring); 3. Locked hinge polypropylene AFO 	<p>Kinematics: ankle motion as well as screw axis of ankle motion;</p> <p>Kinetics: DF/PF, inversion/eversion, add/abduction moments</p>	<ul style="list-style-type: none"> • Variability on the location of the screw axis of the ankle increased substantially in the flexible hinge AFO as compared to the locked hinge AFO; • Only the locked hinge AFO, as compared to the other braces studied, ↑ in stiffness as DF range also ↑; • In the solid ankle AFOs, the screw axis of the ankle shifted posteriorly as trim lines ↓ and overall stiffness ↓ 	VI C
<p>Summary of Evidence</p> <p>This descriptive, level VI study did not use human subject testing, but was able to elaborate our understanding of external bracing stiffness and location of the ankle joint axis in various parts of the range of motion in different types of articulated and non-articulated bracing designs. As such it forms the basis for developing additional research questions. Understanding stiffness is a key component in determining appropriate bracing designs to externally augment the ankle DF moment. Also, an understanding of the movement of the ankle joint axis during normal range of motion is crucial in the development of functional articulated joints.</p>						

Table 4: Standard Articulated AFO: Mechanical Testing

Authors & publication date	Number of subjects & subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Weiss et al 2002 ⁶⁰ (abstract)	10 CVA; ankle PROM WNL (from Eberly ⁶¹); no additional subject description; ambulation independence level not reported	Cross-over design with random order of testing; ≥ 2 week familiarization period with each brace before testing	<ol style="list-style-type: none"> 1. Solid in 5° DF; 2. Articulating with free DF/PF from 10° DF to 10° PF; 3. Articulating with free DF, PF stop at neutral; 4. Shoes only 	<p>Stride analysis: Velocity, stride length & cadence;</p> <p>Kinematics: 3-D hemi LE joint ranges</p>	<ul style="list-style-type: none"> • Walked significantly slower in solid than articulating AFOs due to ↓ cadence and stride length; • ↓ knee flexion in preswing, DF in mid/terminal stance in solid AFO as compared to other conditions; • ↑ knee flexion during loading & DF during swing in all braced conditions; • ↑ hip flexion in initial swing in shoes only condition as compared to brace • Solid AFO impedes limb progression during stance 	IV B
Eberly et al 2003 ⁶¹ (abstract)	11 CVA; at least 6 months post CVA; PF contracture of 5-10°; no additional subject description; ambulation independence level not reported	Cross-over design with random order of testing; ≥ 2 week familiarization period with each brace before testing	<ol style="list-style-type: none"> 1. Solid AFO; 2. DF stop & DF assist AFO; 3. PF stop AFO; 4. Shoes only 	<p>Stride analysis: Gait velocity & stride characteristics;</p> <p>Kinematics: 3-D hemi LE joint ranges;</p> <p>Kinetics: Joint moments at knee & ankle</p>	<ul style="list-style-type: none"> • Gait velocity significantly faster & ↓ knee flexion preswing in solid compared to shoes; • PF ↓ at initial contact and DF ↑ during swing in all brace conditions compared to shoes; • Preswing DF ↓ in solid as compared to dorsi assist brace; • ↑ knee flexion during loading and knee flexion moment at initial contact ↑ in solid & plantar stop; • ↑ knee flexion moment during loading in solid as compared to shoes • Restricted mobility of PF stop and solid AFO is not significantly > than that caused by PF contracture itself 	IV B

Yamamoto et al 1999 ⁷⁸	5 CVA; No additional subject description; ambulation independence level not reported	Cross-over design between 3 AFOs in random order; Case series with descriptive statistics only, no group analysis	1. Articulated polypropylene dorsiflex assist (spring controlled) AFO (DACs) adjustable with DF assist springs from 5 to 20 N•m per 10 ° PF, with an initial ankle angle adjustable from 0-10 ° DF, and with a range of 30° DF and 10°PF from initial ankle angle setting (adjusted appropriately for each subject after observing their gait); 2. Double metal adjustable AFO with PF stop; 3. Solid ankle plastic AFO; 4. No AFO	Kinematics: 3-dimensional measurement of lower extremity; Stride analysis: velocity Subjective opinion: questionnaire to subjects about comfort and use of AFOs	<ul style="list-style-type: none"> • None of the subjects complained about the DACs in terms of weight, use of shoes, and donning/doffing; • ↑ velocity with DACs compared to plastic AFO and no AFO; • Gait patterns were most normalized with DACs 	VI C
<p>Summary of Evidence</p> <p>Yamamoto & colleagues's⁷⁸ most recent work develops the results of their previous research into a clinical model of the instrumented AFO. They obtain similar results in improved gait velocity and parameters to those discussed previously, and subject acceptance of the new design is positive. Although minimal details are available in abstract format, the Weiss⁶⁰ and Eberly⁶¹ studies are the first to tackle directly the issue of articulated versus non articulated bracing designs in the presence of PF/heel cord tightness, a common impairment in chronic stroke patients^{6, 63, 79}. They conclude, logically, that gait velocity and parameters all improved in the articulated as compared to non-articulated AFOs only in subjects with normal sagittal plane passive range of motion (PROM) at the ankle joint. Without available PROM at this joint, articulation of the AFO adds little benefit.</p>						

Table 5: Standard Articulated AFO: Motion Analysis Testing

Authors & publication date	Number of subjects & Subject characteristics	Study design	Bracing comparisons	Outcome measures	Results and conclusions	Level/ grade of evidence
Hachisuka et al 1998 ⁷²	5 CVA; "no longer in inpatient rehab"; Brunnstrom LE Stage IV; no PF contracture; independent ambulators	Cross-over design; All currently using shoehorn type AFO	1. Articulated polypropylene dorsiflex assist (spring controlled) AFO (Yamamoto's clinical AFO design ⁷⁸); 2. Solid ankle polypropylene AFO (current shoehorn type AFO)	Clinical measures: 13 item clinical evaluation form including gait ability, gait pattern, hip joint during swing, toe off, heel strike, knee from heel strike to toe off, equinus, varus, circumduction, and trunk backward tilt during swing, step length; Stride analysis: 10-meter walk at maximum effort; Subjective opinion of braces (weight, noise, appearance, gait on level surfaces, stairs, slopes, up/down from chair & floor, donning/doffing AFO, & overall preference	<ul style="list-style-type: none"> •No significant differences in gait evaluation measures, gait velocity, or subjective evaluation between AFOs; •Subjects all preferred solid AFO (AFO being currently used by subject) to dorsiflex assist AFO 	IV B
Tyson et al 1998 ⁸⁰	4 CVA; 8 months to 3 years post CVA; ¾ with marked spasticity; ¼ independent ambulator	Cross-over design; Case series; A-B (without-with AFO) single case design; ¾ using AFOs ≥ 2 wk. before testing	1. Articulated polypropylene AFO with PF stop and free DF; 2. Shoes only	Stride analysis: velocity, stride/step length, symmetry; Subjective opinion: questionnaire about effects of brace on gait and brace itself	<ul style="list-style-type: none"> •↑ velocity (4/4), more normal stride/step length (4/4) & symmetry (3/4) with AFO; •Subjects (4/4) felt their gait was improved by the AFO, and although some did not like its appearance, they felt walking better was more important than cosmesis 	VI C
Tyson & Thornton 2001 ⁸¹	25 CVA; mean duration post CVA 8.3 months; "able to weight bear & step with weak leg"; could obtain plantigrade position; 19/25 independent ambulators on level surfaces with AFO	Cross-over design; Wore AFO 1 month before testing	1. Articulated polypropylene AFO with PF stop and free DF; 2. Shoes only	Clinical measures: Functional Ambulation Categories (FAC); Stride analysis: velocity, stride/step length, symmetry; Subjective opinion: questionnaire about effects of brace on gait and brace itself	<ul style="list-style-type: none"> •Significantly ↑ function on FAC, velocity, stride length, & cadence with AFO; •Subjects (24/25) were very positive about the effect of the brace on their walking ability and comfort of brace; •Some felt it was too heavy (6/25) or did not like its appearance (5/25); •14/25 could put it on/off independently; •24/25 felt function more important than quality of movement 	IV B

Beckerman et al ²⁸	30 CVA; 5-185 months post CVA (median 34 mo.); "spastic equinus position of foot"; no PF contracture; independent ambulators although PAFO group more impaired than SAFO group initially with average gait velocities of 0.32 m/sec PAFO group & 0.44 m/sec SAFO group, ≥ 5 beats of clonus 6/14 PAFO group, 3/16 SAFO group, ↓ quad strength 11/14 PAFO group, 4/16 SAFO group	Randomized clinical trial; Partially blinded; Each subject used the assigned AFO for 12 wks; Assessed at beginning and end of 12 week period	1. Solid polypropylene AFO (SAFO) set in 5° DF; 2. "Placebo" articulated polypropylene AFO (PAFO) allowing free DF/PF; 3. Shoes only	Stride analysis: walking speed; Clinical measures: motor function, balance, and spasticity as well as Sickness Impact Profile (SIP); Subjective opinion: questionnaire measuring satisfaction, compliance, and side effects	<ul style="list-style-type: none"> • No significant differences were found between groups although higher SIP scores with solid AFO; • No clinically relevant differences between groups; • Compliance wearing AFOs for study period a problem, especially with PAFO, with noncompliers usually switching back to old orthosis; • SAFO users complained of calf muscle stretching with brace set in 5° DF; • PAFO users complained of "wounds on toes", toe clawing, burning sensations, free ankle ROM, and problems donning PAFO 	IIb B
Leung & Moseley 2003 ¹⁹	CVA	Systematic review	See summary Table 2	See summary Table 2	See summary Table 2	I A

Summary of Evidence

Hachisuka and colleague's⁷² compared Yamamoto's⁷⁸ clinical AFO model to the current non-articulating AFOs being worn by 5 stroke patients. Interestingly, this study did not support Yamamoto's⁷⁸ results, finding no difference in gait velocity and parameters, as well as poor subject acceptance of the trial AFO. It should be noted, however, that all subjects were currently using the preferred comparison non-articulating brace.

Tyson and colleague's articles^{80,81} examine the least mobile population of stroke patients identified in this review and found improvements in gait velocity and parameters with an articulated brace condition as compared to a no brace condition. In addition, these subjects clearly felt that, despite issues such as appearance, weight, and independence in donning/doffing the brace, functional improvements resulting from use of the brace were the most important factor.

Beckerman and colleague's work²⁸ represents the only randomized clinical trial in this review. They found no significant difference in gait velocity and clinical measures between a solid and articulating design AFO. The study, however, presents some of the difficulties of conducting randomized clinical trials with the heterogeneous stroke population. With only 14 and 16 subjects in each group, the randomly assigned articulating AFO group was significantly more impaired than the non-articulating AFO group, and this may have influenced the study results. Additionally, there were definite compliance issues identified in this research, probably related to problems such as skin breakdown, lack of adequate DF PROM, and difficulty independently donning the study brace for the 12 week required period of time. Many subjects clearly preferred their old, non-study braces that were more comfortable and functional for them, invalidating some of the research results.

Table 6: Standard Articulated AFO: Clinical Measurement

No studies were located that examined ground reaction designs with the stroke population although Lehmann and colleagues²⁷ did test a double metal upright AFO set in 5° plantarflexion. This is the closest any of the reported literature comes to assessing this bracing category in adult hemiplegic patients.

Table 7: Ground Reaction Articulated AFO: Mechanical Testing, Motion Analysis Testing, Clinical Measurement

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PHYSIOTHERAPY FOR THE LOWER LIMB (R4)

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INTRODUCTION

Among Medicare covered individuals in the United States, stroke is the sixth most common diagnosis of patients discharged from short-stay hospitals.¹ Although the impairments and functional limitations experienced by patients with stroke vary, they are such that a large proportion of patients diagnosed with stroke receive at least some physical therapy services. The scope of these services differs, but the emphasis is often on gait and/or impairments related to it. Given the importance of gait to patients themselves,^{2,3} this emphasis is warranted.

The purpose of this review is to summarize research relevant to physiotherapy interventions for the lower limb. The scope of the review is purposely limited. It is limited in part by necessity; a comprehensive review would result in a day long presentation and book length manuscript. It is restricted also because some interventions within the domain of physical therapy (eg functional electrical stimulation) are addressed by other presenters at this conference. Therefore, this review of literature relevant to patients with stroke will address the following interventions with implications for gait: 1) exercise regimens for the lower limb, 2) traditional gait training and the use of assistive devices (eg canes), 3) training with treadmills and stepping machines, and 4) rhythmic auditory cuing.

The bulk of articles used in this review were identified and supplied through RECAL information services. Other relevant references were identified through searches of databases (eg Medline, CINAHL), my personal files, and the reference lists of relevant articles. Longitudinal experimental and quasi-experimental studies were given the most attention; but where the only evidence available was from cross-sectional studies (eg use of assistive devices), they were exploited as well. Other studies were used when valuable for explanation or qualification.

EXERCISE REGIMENS FOR THE LOWER LIMB

Resistance Exercise

Resistance exercise is widely used by healthy individuals and patients with a variety of diagnoses/disorders with the intent of increasing muscle strength and improving performance at tasks dependent on muscle force production. Despite historical admonitions against such exercises in patients with stroke,⁴ resistance exercise represents a specific intervention that has been employed and studied in patients with stroke. This review includes 11 studies in which resistance exercise was used as a primary intervention (Table 1). In 7 of the studies the effect on a specific gait outcome is noted.

Exercises with weights, elastic or pneumatic resistance, or manual guidance/resistance have been utilized with patients with stroke. Badies et al demonstrated a mean 31% increase in leg-press strength after 4 weeks of leg-press exercise, but some of their subjects were still in the acute phase of

recovery and may have demonstrated improvements that were spontaneous in part.⁵ Inaba et al reported significantly greater strength increases and functional independence at 1 month in a group of patients whose regimen included leg-press exercises.⁶ At 2 months, however, the subjects participating in leg-press training demonstrated neither greater strength nor more functional independence than subjects whose regimens did not include the resistance exercise. Weiss et al, whose subjects trained for 12 weeks using weights and pneumatic resistance, demonstrated bilateral strength improvements in isolated actions of the hip but not in leg-press.⁷ They improved sit-to-stand (STS) performance and some walking and balance measures but not others. The addition of 3 proprioceptive neuromuscular facilitation (PNF) exercises to the regimen of rehabilitation inpatients was not found by Stern et al to influence movement, strength, or functional outcomes. However, only 10 repetitions of the exercises were used per day and the amount of manual guidance/resistance associated with the exercises is not known.⁸ Wang, whose patients participated in 30 minutes of PNF exercise, improved in both gait speed and cadence over the course of 12 treatments.⁹ Patients who had hemiparesis of short duration, unlike those with hemiparesis of long duration, also improved after the first treatment.

Several studies involving exercise with dynamometers have been published. Sharpe and Brouwer reported that 6 weeks of concentric isokinetic training improved knee extension and flexion strength, gait speed, and adjusted activity scores.¹⁰ The training, however, did not result in significant increases in stair climbing or Timed Up and Go (TUG) test performance. At 4 week follow-up, gait speed and adjusted activity scores were still improved. Of isokinetic measures, only knee extension torque at 30°/sec remained improved. Stair climbing speed and TUG performance were not different from baseline. Isokinetic training of 6 weeks was not found by Kim et al to result in increases in composite strength, gait speed, stair climbing speed, or SF-36 physical health scores that were superior to those of a control group.¹¹ Bourbonnais et al trained patients for 6 weeks.¹² Patients whose lower limbs were trained on the dynamometer demonstrated greater improvements in maximum voluntary force, gait velocity, and distance walked in 2 minutes than patients whose upper limbs were trained on the dynamometer.¹² These improvements were retained at 8 week follow-up. Changes in lower extremity Fugl-Meyer scores and TUG, however, did not differ. Eccentric training is also possible with some dynamometers. As patients with spasticity demonstrate less antagonist activation during eccentric than during concentric activation,¹³ it would appear that eccentric training might yield better results. Engardt et al engaged patients with stroke in 6 weeks of either eccentric or concentric training of the knee extensors.¹⁴ Significant increases in both eccentric

and concentric torque were demonstrated in both groups. Neither group was universally superior in improving function. Eccentric training was accompanied by improved weightbearing through the paretic lower limb during STS, whereas concentric training resulted in faster walking speed and duration of swing.

Functional exercises, which use body weight for resistance, were advocated long ago by Hirschberg¹⁵ and have been used in several studies of patients with stroke. The value of such interventions has been examined for both acute and chronic patients. Beginning 1-2 days after admission, Asberg et al had a group of patients with stroke stand from a chair at least once per hour between 8 AM and 8 PM.¹⁶ The treatment continued for 1-2 weeks. Between 5 and 7 days after stroke, a group of patients so treated were significantly less disabled than a control group not performing the STS's. Ten to 12 days and 3 months after stroke, however, the proportion of independent patients was not different between the STS and control group. Monger et al had also trained patients using STS's, but their patients were more than a year post stroke and also performed step-ups and calf-stretches.¹⁷ The training resulted in improved STS performance and walking speed. These findings, along with those of studies in which patients with traumatic brain injury¹⁸ and the elderly^{19,20} have been trained using functional exercise, provide some evidence for the use of such training in patients with stroke.

Other Specific Exercises

Several studies have investigated specific exercises, among them cycling. Cycling, even against higher workloads, appears to "facilitate phasic and coordinated muscle activities" in patients with stroke.^{21,22} Its use as a mode of exercise for patients with stroke, therefore, holds promise. Though most studies in which it has been used employ it in combination with other modalities, two studies have exercised patients with cycling alone (Table 2). In one, eccentric knee extensor strength increased bilaterally but concentric knee extension strength increased only at one speed on the paretic side after training.²³ Neither knee flexion strength nor gait speed increased. In the other study several indicators of exercise capacity during cycling (eg $\dot{V}O_2$, exercise time) increased after training.²⁴ Whether these same variables improved during gait was not indicated.

Multicomponent Exercise Programs

The content of therapy as it is often applied includes a combination of diverse activities. Table 3 summarizes 9 studies of multicomponent exercise programs, 8 of which were randomized (at least in part).²⁵⁻³³ The activities incorporated in the regimens included, but were not limited to: walking (overground or treadmill), cycling, strengthening exercises, stretching exercises, and balance activities. The regimens had durations of 4 to 20 weeks and included acute, subacute, and chronic patients. Subjects in treatment groups tended to improve in measured variables, though not necessarily significantly more than subjects in control or upper extremity treatment groups/arms. Walking speed increased in 8 of the studies in which it was measured. The increases in

6 of the studies were significant,^{25,26,27,28,31,32} though in 1 the lower-limb treatment group differed from the control group but not the upper-limb treatment group.²⁷

TRADITIONAL GAIT TRAINING AND USE OF ASSISTIVE DEVICES

Traditional Gait Training

Like other aspects of motor performance, gait can be expected to improve during the first few months after stroke. Whether traditional gait training contributes to such improvements is not certain. Hesse et al documented improvements over the course of a 4-week rehabilitation program based on neurodevelopmental technique (NDT).^{34,35} Specifically, they noted that lower extremity muscle strength, gait speed, step climbing speed, stance duration, and weight acceptance and push-off improved significantly. Gait and step climbing endurance did not improve. The failure of these and some key symmetry values to improve led Hesse et al to question the advisability of intensive NDT focused on the restoration of physiological gait. Their concerns notwithstanding, they did note in another study that NDT techniques were accompanied by real-time improvements in gait velocity and stride length, cycle parameters (affected leg stance period), symmetry, hip motion, and muscle activation.³⁶ For 5 patients who were monitored an hour after therapy, there was no residual effect on any gait variable.

In cases of more chronic stroke, improvements in motor status that accompany physical therapy interventions might be attributed with more confidence to the therapy. Wade et al engaged patients who were 2-7 years post stroke in a problem oriented intervention.³⁷ Problems relevant to gait included abnormal gait patterns, unsafe walking outside, unstable to stand alone, difficulty changing direction, equipment and exercise tolerance. They demonstrated that gait speed increased significantly after treatment but that performance declined after the treatment was withdrawn. Overall motor status and mobility, Barthel walking independence score, and outdoor walking did not change with treatment. In an uncontrolled case series, Rodriguez et al studied the efficacy of home based therapy on patients who were 1-5 years post stroke.³⁸ They employed ankle foot orthoses and worked on range of motion, balance, weight shifting, muscle recruitment out of synergy, and correction of gait deviations. Training extended over an average 22 months and 35 contact hours. It resulted in significant improvements in Wisconsin Gait Scale scores. Patients judged that the quality of their functional activities improved. Fear of falling diminished in a subset of patients.

Use of Assistive Devices

Assistive devices such as canes and walkers provide several biomechanical advantages. They can be used to unload a lower limb³⁹ or to increase stability.⁴⁰ The former is achieved by the assumption of load through one or both upper limbs via the device. The latter can be accomplished through a widening of the base of support and through the provision of additional sensory feedback, through one or both upper limbs via the device.⁴¹ These facts notwithstanding, there

is little research on the effects of device use on gait following stroke. I found no longitudinal research addressing gait training with assistive devices. Several cross-sectional explicatory experiments, however, have been performed (Table 4). These experiments did not show the use of canes to be consistently advantageous, at least for patients who are capable of walking without them.^{42,43} Tyson did not show a difference in patients' walking performance or the weight support they took when walking with a cane, a high cane, or a tripod cane.⁴⁴ Tyson and Ashburn, however, suggested that patients who had mild weakness and were good walkers were either not helped or were hindered by canes while patients who had severe weakness and were poor walkers benefited from using a device.⁴⁵ Tyson's finding that severity of weakness was related to aid contact time and percentage weight taken through the aid⁴⁴ is consistent with this suggestion. Whether walking with or without a device, patients whose upper limb has not recovered sufficiently, may benefit from having it in a sling when they walk. Yavuzer and Ergin found that such patients walked faster, had a longer paretic side stance phase, and had decreased double support time when wearing a sling (compared to when they were not wearing the sling).⁴⁵

For patients requiring more support than can be supplied through a cane, rolling platform walkers can be employed.⁴⁶ These walkers may have the additional advantage of engaging the paretic upper extremity.⁴⁴ This may not only be therapeutic for the limb but foster a better gait as well.

TRAINING WITH TREADMILLS AND STEPPING MACHINES

Treadmills

Although long used for aerobic training, treadmills have been employed only since the 1990's for training patients whose gait is compromised by stroke. The moving belt of the treadmill acts to "force use" and entrain stepping. Its adjustable speed allows this to be done at a rate matched to patient status. Especially when combined with weight unloading, treadmill walking has real time benefits for gait. Researchers have shown that patients walking on the treadmill demonstrate increased stance symmetry,⁴⁸⁻⁵¹ a reduced time of double support,^{51,52} an increased stance duration (as % of cycle) on the paretic side,⁴⁹⁻⁵¹ a more upright posture,⁴⁹ and decreased spasticity and cocontraction at the ankle.⁵⁰

At least 15 longitudinal studies of treadmill training for patients with stroke have been published to date (Table 5). Early studies were nonrandomized trials involving mostly patients with chronic stroke. In two of these studies, Hesse et al, trained previously nonambulatory patients with a weight unloading treadmill system, 5 days per week.^{53,54} In both studies the patients realized significant improvements in Functional Ambulation Category scores and gait speed without concomitant changes in muscle strength or tone. In the second study, which involved the use of an ABA design for each of 7 patients, improvements in gait occurred only during the treadmill training phases.⁵⁴ Among chronic patients functioning well enough not to require body weight assistance, Macko and others have

shown in nonrandomized trials that treadmill training can elicit improvements in fitness and efficiency measures obtained during treadmill walking,^{55,56} in overground walking speed and cadence,⁵⁷ and in some measures of knee flexion strength.⁵⁸

Studies involving randomization of some kind have compared treadmill training to usual physical therapy, treadmill training to traditional gait training, treadmill training with and without body weight support, and treadmill training at various speeds. Liston et al employed a cross-over trial to compare 60 minutes of treadmill training to physiotherapy including 31 possible interventions.⁵⁹ Multiple improvements were noted among treated patients, but there were no significant differences in improvements over the two arms of the study. Improvements realized over the treadmill training arm approached significance for 10 meter walk time and steps over 10 meters. Hamzat found that patients engaged in treadmill training had physiologic cost indexes that were significantly less than those of patients engaged in routine therapy. In comparing treadmill training to traditional training,⁶⁰ Laufer et al demonstrated that subjects of the former improved in their Functional Ambulation Category and balance while the subjects of the traditional floor training group did not improve.⁶¹ Nilsson et al showed that assorted variables improved with treatment in patients with acute/subacute stroke.⁶² Improvements, however, did not differ between patients engaged in a motor relearning program and patients participating in treadmill training with bodyweight unloading. Teixeira da Cunha et al showed that patients participating in supported treadmill training improved significantly more in oxygen consumption on a cycle ergometer than patients participating in regular gait training.⁶³ Training on the treadmill, however, did not result in better improvements in Functional Ambulation Category scores, Functional Independence Measure locomotion scores, or walking speed, distance, energy expenditure, or metabolic cost.^{63,64} When compared to aggressive brace assisted gait training of up to 45 minutes per day, body weight supported treadmill training resulted in greater improvements in speed and endurance only among patients who had hemisensory and hemianoptic deficits in addition to hemiparesis.⁶⁵

The improvements realized with treadmill training may be accentuated by the use of body weight unloading and the optimization of belt speed. Visitin et al, who compared patients walking on a treadmill with patients walking on a treadmill with up to 40% weight support, found that patients trained with weight support demonstrated better walking speed and endurance after training.⁶⁶ At 3 month follow-up, they still had better motor recovery and walking speed. Their balance and walking speed, however, were not significantly better. Pohl et al examined the benefits of conventional gait training and treadmill gait training that was speed dependent or limited progressive.⁶⁷ While both treadmill alternatives resulted in significantly better improvements than conventional gait training, speed dependent treadmill training resulted in greater improvements in gait speed and cadence as well as Functional Ambulation Category scores.

Stepping Machines

The need for assistance with body positioning and weightshifting, as well as for advancing the paretic lower limb, makes treadmill training impracticable for severely involved patients in most clinical settings. Stepping machines, like treadmills, allow for the repetitive practice of stepping; but they do so without the concomitant need for so much assistance. Simple stepping machines have been available for over 20 years. Glasser did not find the addition of training with such a machine to result in improvements in gait beyond those obtained from a standard rehabilitation program.⁶⁸

More recently, Hesse et al developed a mechanized gait trainer that "simulates the phases of gait," provides body weight support as required, and "controls the center of mass in the vertical and horizontal directions."⁶⁹ Muscle activation patterns and kinematics when healthy individuals exercise on the machine are similar to those they demonstrate when walking on a treadmill.⁶⁹ By comparing patients with stroke while they walked on a treadmill and on a mechanized gait trainer, Hesse et al found that patients required less assistance while on the mechanized trainer.⁷⁰ They also showed that walking on the gait trainer was associated with greater symmetry. Gait on the trainer was accompanied by a significantly higher level of activation of the paretic biceps femoris but a significantly lower level of activation of the nonparetic tibialis anterior. Compared to walking on the treadmill, walking on the gait trainer resulted in significantly greater paretic hip flexion (swing) and extension (stance) but significantly less paretic knee flexion (swing) and ankle plantar flexion. At least 5 studies have been conducted using the mechanized gait trainer (Table 5). Three studies have presented the results of mechanized gait training on patients who were severely disabled by stroke. In the first, Hesse et al reported that 2 previously nonambulatory patients achieved independent ambulation with a cane and substantial improvements in motor performance and gait speed.⁷¹ In the second, Hesse et al demonstrated significant improvements in motor performance, functional ambulation, and in gait velocity, cadence, and stride length.⁷² In comparing training with the gait trainer to that with a treadmill, Werner et al found that improvements in functional ambulation were greater over the time patients trained on the gait trainer.⁷³ Improvements in gait velocity and Rivermead Motor Assessment scores did not differ significantly between the training options.

RHYTHMIC AUDITORY CUING

Rhythm, whether provided in isolation (eg via metronome) or imbedded in music, has been employed to facilitate rhythmic activities such as gait. Thaut et al found that patients with stroke demonstrated several notable changes in gait when walking to the accompaniment of music with an imbedded rhythm. Specifically, they had increased stance time on the paretic lower limb, improved stride symmetry, increased gastrocnemius activation during midstance/push-off, and decreased gastrocnemius activation during swing phase.⁷⁴ Favorable changes associated with rhythmic cuing in another study included: a) increased symmetry between

sides in stride lengths and hip range of motion, and b) reduced vertical displacement of the center of mass.⁷⁵ The benefits of rhythmic cuing appear to carry over from individual sessions. Thaut et al demonstrated that patients whose treatment included 2 daily sessions of gait training with auditory cuing improved more than patients whose gait training was not so augmented.⁷⁶ Improvements in speed and stride length were significantly greater.

CONCLUSIONS

In this review I have focused on 4 major classifications of interventions not emphasized by other reviewers. There are other categories of interventions that I have intentionally omitted (eg balance training, electromyographic biofeedback). Drawing confident conclusions from the literature has proven difficult because: 1) results often vary depending on the outcome measured, 2) some study designs (eg pre-post) do not lend themselves to classification using the levels of evidence advocated by Greenhaugh⁷⁷ (such studies were classified according to the Center for Evidence Based Medicine [CEBM] scheme), and 3) studies are often underpowered (sample sizes of groups are frequently < 15).

Nevertheless, I believe that the literature is sufficient to support a few graded recommendations and to identify gaps in the research literature and key questions. I will do so with commentary hereafter.

RECOMMENDATIONS

1. Strength training bouts of adequate volume, if carried out ≥ 2 days/week for ≥ 3 weeks, will result in increases in strength beyond those realized in the absence of such training. (Grade A) The increases will vary depending on the nature of the actions trained and measured.

2. Strength training bouts of adequate volume, if carried out ≥ 2 days/week for ≥ 3 weeks, can result in increases in function beyond those realized in the absence of such training. (Grade B) Such increases are not as likely as increases in strength. The increases will vary depending on the nature of the actions trained and the functions measured.

3. Adequate volumes of aerobic exercise (via cycle or treadmill), if carried out alone or in combination with other exercise ≥ 3 days/week for ≥ 10 weeks, will result in increased aerobic capacity beyond that realized by patients not so training. (Grade A) These increases do not necessarily carry over to function.

4. Nonambulators and poor ambulators participating in treadmill training ≥ 3 days/week for > 3 weeks improve more in gait than similar patients not so treated. (Grade B) Treadmill training for such patients, however, requires special equipment and attendant assistance.^{78,79} The benefits of treadmill training might not be attributable to the treadmill since positive results have been realized through use of a gait trainer⁷³ and vigorous braced gait training.⁶⁵ Still, for severely involved patients with stroke, there may be no other practical way to approximate the more than 7000 steps per day taken by independent community walkers.⁸⁰

Study	Subjects	Intervention	Findings	Level of Evidence
Asberg (1999)	63 acute patients on general medical wards: 30 treatment, 33 control	Duration: 1-2 weeks beginning 1-2 days post admission. Frequency: ≥ once/hour between 8AM & 8PM. Treatment: patients encouraged by nurse or staff to stand from bed or chair	1. Significantly higher proportion of severely disabled patients in control group ($p < .001$) 5-7 days post stroke. 2. Proportion of severely disabled patients not significantly different 10-12 days post stroke or 3 months post stroke.	Randomized controlled trial Level II (Greenhulgh)
Badies et al (2002)	56 residential rehabilitation patients (3 wks – 10 yrs post stroke)	Duration: 4 weeks Frequency: Not stated Treatment: 3-5 sets of 20 repetitions of leg press at 30-50% max	Leg press strength increased a mean 31.0% (significance not stated).	Pre-post trial Level IV (CEBM)
Bourbonnais et al (2002)	25 chronic patients: 13 paretic upper limb training, 12 paretic lower limb training	Duration: 6 weeks Frequency: 3 days/week Treatment: multi-directional static dynamometer with force feedback	1. Maximum voluntary efforts of the lower limb improved significantly (39-81%) in all directions in the group training the lower limb. 2. Gait velocity and distance walked in 2 minutes improved significantly more in lower limb training group. That group's increases were significant at the end of training and at 8 week follow-up. 3. Changes in lower extremity Fugl-Meyer scores and TUG did not differ between groups.	Randomized controlled trial Level IIb (Greenhulgh)
Engardt et al (1995)	20 chronic ambulatory patients: 10 concentric training, 10 eccentric training	Duration: 6 weeks Frequency: 2 days/ week Treatment: up to 15 sets of either concentric or eccentric isokinetic knee extensions on dynamometer set at 60, 120, & 180° / sec	1. Significant increases in knee extension torque demonstrated under concentric and eccentric conditions at all speeds in both groups. 2. Body weight distributed on the paretic lower limb during SIT-TO-STAND increased in eccentric group but not concentric group. 3. Self-selected and fast walking speed and duration of swing during self-selected speed increased significantly in concentric group but not eccentric group. Duration of swing during fast walking speed not increased in either group.	Randomized trial Level IIb (Greenhulgh)
Inaba et al (1973)	67 rehabilitation inpatients unable to walk independently: 28 functional training & stretching (FT&S) plus resistance exercise, 23 FT&S plus active exercise, 26 FT&S only	Duration: 1-2 months. Frequency: Daily Treatment: Resistance exercise= Leg press (5 reps @ ½ maximum & 10 reps at maximum). Active exercise= Daily class of hip, knee, and trunk exercises, 15 min unresisted cycling.	1. At 1 month, strength gain significantly higher ($p < .02$) in the FT&S plus resistance exercise group. 2. At 1 month, proportion of patients showing improvement in ADLs significantly ($p < .05$) higher in FT&S plus resistance exercise group. 3. These superior outcomes not demonstrated at 2 months.	Randomized trial Level IIb (Greenhulgh)
Kim et al (2001)	20 patients with residual weakness (> 6 months post stroke): 10 isokinetic training, 10 control	Duration: 6 weeks Frequency: 3 days/ week Treatment: Isokinetic training= 3 sets of 10 max concentric hip flexion/extension, knee flexion/extension, and ankle dorsiflexion/ plantarflexion of paretic side. Control= passive motion instead of max efforts.	1. Greater increases in composite strength in the training group were not significant. 2. No significant differences were found between groups in increases in gait speed, stair-climbing speed, or SF-36 physical health scores.	Randomized controlled trial Level IIb (Greenhulgh)

Monger et al (2002)	6 patients discharged from all rehabilitation services (> 1 year post stroke)	<u>Duration:</u> 3 weeks <u>Frequency:</u> 3 days/ week <u>Treatment:</u> Supervised task specific (3 sets of up to 10 SIT-TO-STAND, 3 sets of 10 step-ups, 10 calf stretches), home pro-gram of same tasks	1. Significant improvements in Motor Assessment Scale score for SIT-TO-STAND, time to peak vertical ground reaction force through the affected lower limb during SIT-TO-STAND, and mean walking speed. 2. "Grip strength, which was not trained," did not improve	Pre-post trial Level IV (CEBM)
Sharp & Brouwer (1997)	15 ambulatory patients (> 6 months post stroke)	<u>Duration:</u> 6 weeks <u>Frequency:</u> 3 days/week <u>Treatment:</u> 40 minute exercise sessions (warm- up for 5 minutes consisting of stationary cycling and stretches, 3 sets of 6-8 maximal isokinetic efforts on Orthotron at each of 3 speeds, and cool-down).	1. After 6 weeks of training, knee extension and flexion strength, gait speed, and adjusted activity score increased significantly (p<.05). 2. After 6 weeks of training, spasticity, stair climbing, and Timed Up and Go did not change significantly. 3. At 4 week follow-up, gait speed and the adjusted activity score were still improved. Only knee extension torque at 30 degrees/ sec remained significantly increased. 4. At 4 week follow-up spasticity, stair climbing, and Timed Up and Go were not significantly different from baseline.	Pre-post trial Level IV (CEBM)
Stern et al (1970)	62 rehabilitation inpatients: 31 facilitation treatment, 31 no "specialized" exercise	<u>Duration:</u> course of in-patient stay <u>Frequency:</u> daily <u>Treatment:</u> 10 re-petitions of PNF exercises including 3 lower extremity exercises performed while supine.	1. No significant difference between groups in change in Motility Index. 2. No significant difference between groups in change in knee muscle strength. 3. No significant difference between groups in change in independence in activities of daily living.	Randomized trial Level IIb (Greenhough)
Wang (1994)	20 patients: 10 short duration (2.8-5.6 months post-stroke), 10 long duration (12.7-18.5 months)	<u>Duration:</u> 4 weeks <u>Frequency:</u> 3 days/week <u>Treatment:</u> PNF to pelvic region (10 minutes each of rhythmic initiation, slow reversal, and agonistic reversal)	1. Compared to baseline, the short duration group improved significantly in gait speed and cadence after 1 and after 12 treatments. 2. Compared to baseline the long duration group declined significantly in gait cadence but not speed after 1 treatment, but increased significantly in both after 12 treatments.	Pre-post trial Level IV (CEBM)
Weiss et al (2000)	7 home-dwelling patients, > 60 years old (> 1 year post stroke)	<u>Duration:</u> 12 weeks <u>Frequency:</u> 2 days/week <u>Treatment:</u> Weight and pneumatic machine training of hip flexion, abduction, and extension, knee extension and leg press	1. Strength of hip flexion, abduction, and extension improved significantly in both the paretic and nonparetic lower limbs, but strength of leg press did not increase significantly. 2. Repeated chair stands improved, as did scores on the Motor Assessment Scale, walking subscale of the Motor Assessment Scale, and Berg Balance scale. 3. Stair climbing speed, habitual gait speed, and unilateral stance time did not improve.	Pre-post trial Level IV (CEBM)

Table 1. Summary of Studies of Resistance Exercise for Patients After Stroke

Study	Subjects	Intervention	Findings	Level of Evidence
Perell et al (2001)	8 male patients (.5-13 years post stroke)	Duration: 4 weeks Frequency: 3 times/ week Treatment: Recumbent cycling (12 trials of 1 minute)	1. Walking speed increased but not significantly (p=.069) 2. Excepting eccentric knee flexion torque at 90°/sec on the good side, all strength measurements increased. Eccentric knee extension torque increased significantly at both speeds on both sides. The only significant concentric torque increase was for knee extension of the involved side at 60°/sec.	Pre-post trial Level IV (CEBM)
Potempa et al (1995)	42 patients (14-1098 days post rehabilitation): 19 exercise, 23 control	Duration: 10 weeks Frequency: 3 times/ week Treatment: Cycle training = 30 min sessions, load increased from 30 to 50% of max effort over first 4 weeks. Control = 30 min passive range of motion.	1. Exercise group improved significantly more than control group in cycling oxygen consumption, workload, and exercise time. 2. Fugl-Meyer scores did not improve in either group.	Randomized controlled trial Level IIb (Greenhalgh)

Table 2. Studies of Cycling for Patients with Stroke

Study	Subjects	Intervention	Findings	Level of Evidence
Dean et al (2000)	9 patients (> 3 months post stroke): 5 training, 4 control	Duration: 4 weeks Frequency: 3 days/week Treatment: One hour task related training, under different conditions	1. Immediately after training and 2 months thereafter the training group demonstrated significantly (p<.05) greater improvements in 6 minute walk test, walking speed, and step test. 2. Immediately after training, the training group demonstrated significantly greater improvements in ground reaction force during sit-to-stand. 3. Neither immediately after training nor 2 months thereafter did the training group improve more at the timed up and go test.	Randomized controlled trial Level IIb (Greenhalgh)
Duncan et al (1998)	20 minimally and moderately impaired patients (30-90 days post stroke): 10 exercise, 10 control	Duration: 8 weeks supervised exercise followed by 4 weeks of independent exercise Frequency: Supervised exercise 3 days/week Treatment: 1.5 hours for: 10 minute warm-up of stretching and flexibility, assistive and resistive exercises using PNF or Thera-band, functional exercises, balance exercises, walking, and bicycle ergometry.	1. Exercise group demonstrated significantly greater improvements in lower extremity Fugl-Meyer scores and gait speed. 2. Exercise group demonstrated non-significantly greater improvements in Berg Balance scores, 6 minute walk distance, Barthel ADL scores, instrumental ADL scores, and physical functioning (SF-36 subscale).	Randomized controlled trial Level IIb (Greenhalgh)

Kwakkel et al (1999)	89 acute: 26 lower extremity training, 29 upper extremity training, 34 control	<p>Duration: 20 weeks Frequency: 5 days/ week. Treatment: Lower extremity treatment group = 30 minutes of "sitting, standing, and weight-bearing exercises during standing and walking, with an emphasis on achieving stability and increasing gait velocity." Treadmill training if equipment available. Strengthening exercises.</p>	<ol style="list-style-type: none"> 1. Lower extremity treatment group had significantly higher Barthel index and functional ambulation scores at 6, 12, & 20 weeks than the control group. 2. Lower extremity treatment group had significantly higher Barthel index and functional ambulation scores at 6 weeks than the upper extremity training group. 3. Comfortable and maximum walking speeds of the lower extremity training group were significantly faster than those of the control group but not those of the upper extremity training group at 6, 12, and 20 weeks. 4. At 26 weeks, there were no significant differences between groups in any variable. 5. Use of walking aids, Sickness Impact Profile, Nottingham Health Profile, and Frenchay Activities Index did not differ between groups at any time. 	Randomized controlled trial Level IIb (Greenhough)
Kwakkel & Wagenaar (2002)	53 acute (randomized within 14 days of stroke): 17 lower extremity treatment, 17 upper extremity treatment, 18 control	<p>Duration: 20 weeks Frequency: 5 days/ week Treatment: 30 minutes. Lower extremity treatment group= focused on "tasks such as turning over and maintaining sitting and standing balance" and improvement in "symmetry in interlimb coordination during walking."</p>	<ol style="list-style-type: none"> 1. Comfortable walking speed of lower extremity training group improved significantly more than upper extremity training group ($p=.039$) and the control group ($p=.022$). 2. Changes in maximum walking speed were not different between groups. 3. Changes in the continuous relative phase of the paretic and nonparetic limbs did not differ significantly between groups. 	Randomized controlled trial Level IIb (Greenhough)
Richards et al (1993)	27 acute patients: 10 early task specific, 8 early conventional, 9 conventional	<p>Duration: 5 weeks. Frequency: Twice daily Treatment: mean 1.7 hours/day of task specific training (including tilt table, limb loading, resistance exercises with Kinetron, and treadmill).</p>	At 6 weeks, gait speed of task specific training group nonsignificantly higher than conventional groups (after controlling for lower limb status using the Fugl-Meyer leg score). Moderate (.58) effect size noted.	Randomized trial Level IIb (Greenhough)
Rimmer et al (2000)	35 African-American patients (> 6 months post onset)	<p>Duration: 12 weeks Frequency: 3 days per week for 12 weeks Treatment: 60 minutes total. 30 minutes cardiovascular endurance (stepper, cycle, treadmill, or elliptical cross-trainer), 20 minutes muscle strength and endurance (resistance including leg press and leg curl), 10 minutes stretching.</p>	<ol style="list-style-type: none"> 1. Cardiovascular fitness measured on <u>cycle ergometer</u> increased significantly ($p<.01$) more in treatment group <ol style="list-style-type: none"> a. peak $\dot{V}O_2$ ($F=19.58$, $\eta^2=.33$) b. time to exhaustion ($F=8.49$, $\eta^2=.18$) c. maximum workload ($F=16.53$, $\eta^2=.29$) 2. Leg press strength increased significantly ($p<.01$) more in treatment group ($F=108.59$, $\eta^2=.70$). 3. Sit and reach test results increased significantly ($p<.01$) more in treatment group ($F=8.14$, $\eta^2=.15$) 	Randomized controlled cross-over trial Level IIa (Greenhough)

<p>Teixeira-Salmela et al (1999)</p>	<p>13 ambulatory patients (> 9 months post stroke): 6 training, 7 control</p>	<p><u>Duration:</u> 10 weeks <u>Frequency:</u> 3 days/week <u>Treatment:</u> 60-90 minute supervised exercise sessions. Warm-up of cali-thenics & stretching, aerobic exercises (up to 20 minutes each of walking, stepping, cycling), strength training (up to 30 minutes using body weight, weights, and Therabands)</p>	<ol style="list-style-type: none"> 1. Adjusted activity score, quality of life, and comfortable walking speed all improved significantly more in the exercise group than in the control group 2. Significant improvements were demonstrated in gait speed, stair climbing speed, adjusted activity score, quality of life, and total peak torque at the knee. 3. Tone did not change significantly 	<p>Randomized controlled trial and pre-post trial Level IIa (Greenhaulgh)</p>
<p>Teixeira-Salmela et al (2001)</p>	<p>13 ambulatory patients (> 9 months post stroke)</p>	<p><u>Duration:</u> 10 weeks <u>Frequency:</u> 3 days/ week <u>Treatment:</u> 60-90 minute supervised exercise sessions. Warm- up of calisthenics & stretching, aerobic exercises (up to 20 minutes each of walking, stepping, cycling), strength training (up to 30 minutes using body weight, weights, and Therabands)</p>	<ol style="list-style-type: none"> 1. Gait speed, cadence, and stride length increased significantly. 2. Increases in power and positive work were also noted. 3. Double support (%), stance (%), and symmetry ratio did not change. 	<p>Pre-post trial Level IV (CEBM)</p>
<p>Werner & Kessler (1996)</p>	<p>40 outpatients (> 1 year post stroke): 28 treatment, 12 control</p>	<p><u>Duration:</u> 12 weeks <u>Frequency:</u> 4 days/week <u>Treatment:</u> 1 hour of physical therapy & 1 hour of occupational therapy. Orientation toward functional tasks, strengthening, stretch- ing, mobilization, and muscle retraining/ facilitation.</p>	<ol style="list-style-type: none"> 1. Improvement in FIM motor domain significantly greater in treatment than in control group after 3 months. Specific potentially relevant items increasing significantly included dressing, bathing, stairs, and tub/ shower transfers. 2. FIM motor domain did not increase significantly between 3 and 9 months. 3. Sickness Impact Profile improved significantly more in the treatment group than in the control group after 3 months. The physical and dimension improved significantly. Specific relevant categories increasing significantly included body care and movement, household management, and ambulation. 4. Brunnstrom motor recovery rating increased significantly after 3 months but did not improve further during the next 6 months. 5. Timed walking, stair climbing and dressing did not improve significantly 	<p>Randomized controlled trial Level IIb (Greenhaulgh)</p>

Table 3. Studies of Multicomponent Exercise Interventions for the Lower Extremity

Study	Subjects	Intervention	Findings	Level of Evidence <i>Comments</i>
Kuan et al (1999)	15 ambulatory patients (3-43 weeks post stroke)	Ambulation with and without cane	1. No significant difference in walking speed, stronger side step length, or stance period, single support period, double support. 2. Cadence was significantly faster and step width was significantly wider without the cane. Pelvic width/ankle spread was significantly greater with the cane. Stride period and length and step length of the affected side were longer with the cane	Explicatory experiment Level V (Greenhulgh)
Tyson (1998)	15 independently ambulatory patients (> 3 months post stroke)	Ambulation with cane, high cane, and tripod cane	No significant difference in any gait variable during walking with the 3 devices: speed, % body weight taken through cane, contact time, base of support, lateral shift.	Explicatory experiment Level V (Greenhulgh)
Tyson & Ashburn (1994)	20 independently ambulatory patients (3-204 months post stroke)	Ambulation with no aid, cane, high cane, and tripod cane	1. No aid was consistent in yielding better performance. 2. 12 patients "consistently walked best with an aid or no aid." Aids tended to be helpful for patients who were poor walkers but either of no use or detrimental for good walkers.	Explicatory experiment Level V (Greenhulgh)
Yavuzer & Ergin (2002)	31 ambulatory patients (24-75 days post stroke)	Ambulation with or without single strap sling.	1. Wearing the sling resulted in significantly faster gait, longer percentage stance phase on the paretic side, shorter double support time, less pelvic excursion, and greater peak vertical force. 2. Wearing the sling did not alter step time or length or excursion of the hip, knee, or ankle.	Explicatory experiment Level V (Greenhulgh)

Table 4. Results of Explicatory Experiments Examining the Effects of Cane Use on Gait Performance on Cane Use

Study	Subjects	Intervention	Findings	Level of Evidence
Hamzat TK (2002)	46 patients with stroke: 24 routine therapy, 22 treadmill training	Duration: 10 weeks. Frequency: 3 days/ week Treatment: up to 15 minutes treadmill training vs routine physiotherapy	Physiologic cost index significantly lower in the treadmill training group after training	Randomized trial Level IIa (Greenhulgh)
Hesse et al (1994)	9 nonambulatory patients (54-414 days poststroke)	Duration: 5 weeks Frequency: 5 times/ week Treatment: Progression from 15-30 minutes of weight supported treadmill training,	1. Significant improvements in Functional Ambulation Category, balance, and Rivermead Motor Assessment (gross function & leg-trunk) scores, gait speed, cadence, and stride length. 2. No significant change in muscle tone or strength.	Pre-post trial Level IV (CEBM)
Hesse et al (1995)	7 nonambulatory patients (> 3 months poststroke)	Duration: 3 weeks Frequency: 5 sessions/ week. Treatment: Bobath physiotherapy versus treadmill training with partial bodyweight support.	1. Functional Ambulation Categories increased significantly only during the treadmill training phases. 2. Gait speed increased significantly only during the treadmill training phases. 3. Gait cadence and stride length increased significantly only during the initial treadmill phase. 4. Rivermead Motor Assessment scores (gross and leg and trunk) did not improve differently over the phases. 5. Muscle strength and tone did not change significantly over any phase.	Single case ABA Level IV (CEBM)

<p>Kosak & Reding (2000)</p>	<p>56 patients with Functional Independence Measure walking scores ≤ 3 (40 ± 3 days post stroke): 34 aggressive brace assisted walking, 22 partial body weight supported treadmill training.</p>	<p><u>Duration:</u> Inpatient stay. <u>Frequency:</u> 5 days/week. <u>Treatment:</u> In addition to traditional physical therapy, up to 45 minutes of gait training per day (assisted walking or body weight supported treadmill).</p>	<p>1. Both groups improved significantly in ambulatory speed and endurance. 2. Overall the groups did not differ in: speed, endurance, or requirements for orthosis at discharge. 3. Among patients with hemiparesis-hemisensory-hemianopic deficits, greater improvements in speed and endurance were demonstrated by the treadmill training group.</p>	<p>Randomized Trial Level IIa (Greenhulgh)</p>
<p>Laufer et al (2001)</p>	<p>25 patients ambulatory patients (< 90 days poststroke): 12 floor walking training, 13 treadmill training</p>	<p><u>Duration:</u> 3 weeks. <u>Frequency:</u> 5 sessions/week <u>Treatment:</u> Additional gait training (floor or treadmill) of 8-20 minutes.</p>	<p>The treadmill training group improved significantly in Functional Ambulation Category scores and standing balance test scores but the floor training group did not.</p>	<p>Randomized trial Level IIa (Greenhulgh)</p>
<p>Liston et al (2000)</p>	<p>18 patients with cerebral multi-infarct states</p>	<p><u>Duration:</u> 4 weeks <u>Frequency:</u> 3 days/week. <u>Treatment:</u> 60 minutes of treadmill training or physiotherapy consisting of 31 interventions in 3 modules.</p>	<p>1. Significant improvements over 8 weeks in: sit-to-stand time, 10m walk time, steps over 10 meters, gait velocity, step length, 'S' test time, single leg stance time. 2. No significant improvement in width of base during walking, balance or gait sections of ADL mobility scale or Nottingham extended ADL scale. 3. No significant difference in improvements over 2 arms of trial, but compared to physiotherapy arm, improvements over treadmill approached significance for 10 meter walk time ($p=.06$) and steps over 10 meters ($p=.07$).</p>	<p>Cross-over trial Level IIb (Greenhulgh)</p>
<p>Macko et al (1997)</p>	<p>9 patients (> 8 months post stroke)</p>	<p><u>Duration:</u> 6 months <u>Frequency:</u> 3 days/week <u>Treatment:</u> Up to 40 minutes of treadmill training.</p>	<p>Significant reduction in energy expenditure, oxygen consumption, respiratory exchange ratio, and heart rate during submaximum treadmill walking.</p>	<p>Pre-post trial Level IV (CEBM)</p>
<p>Macko et al (2001)</p>	<p>19 ambulatory (> 6 months post stroke)</p>	<p><u>Duration:</u> 6 months <u>Frequency:</u> 3 times/week <u>Treatment:</u> Up to 40 minutes of treadmill walking.</p>	<p>1. After 6 months patients demonstrated significant improvements in treadmill measured peak oxygen consumption, economy of gait, peak work load, and fractional utilization. 2. There was little improvement between 3 and 6 months.</p>	<p>Pre-post trial Level IV (CEBM)</p>

Nilsson et al (2001)	60 patients < 70 years (< 8 weeks post- stroke): 28 treadmill training with body weight support, 32 walking training according to Motor Re- learning Programme.	<p>Duration: Inpatient rehabilitation stay (1-4 months).</p> <p>Frequency: 5 days/ week .</p> <p>Treatment: In addition to standard physical therapy, 30 minutes of gait training (treadmill training with body weight support) or walking training according to Motor Relearning Programme</p>	All variables improved, but there was no significant difference in the groups' improvements at discharge or 10-month follow-up in Functional Independence Measure, walking velocity, Functional Ambulation category, Fugl-Meyer Stroke Assessment, and Berg Balance Scale scores.	Randomized trial Level IIb (Greenhalgh)
Pohl et al (2002)	60 ambulatory (> 4 weeks post stroke): 20 conventional gait training, 20 speed dependent training, 20 progressive training.	<p>Duration: 4 weeks</p> <p>Frequency: 3 times/ week.</p> <p>Treatment: In addition to 45 minutes of conventional training, 45 minutes of gait training based on PNF and Bobath principles; 30 minutes of structured speed dependent treadmill training, or 30 minutes of limited progressive treadmill training.</p>	<ol style="list-style-type: none"> Both the treadmill training groups demonstrated significantly greater improvements in gait speed, cadence, and Functional Ambulation Category scores than the conventional gait training group. The speed dependent treadmill training group also showed significantly greater improvements in these variables than the progressive treadmill training group. Improvements in stride length were significantly greater in the speed dependent group than in the other 2 groups, but were not different between the two. 	Randomized trial Level IIa (Greenhalgh)
Silver et al (2000)	5 patients (> 6 months post stroke)	<p>Duration: 3 months</p> <p>Frequency: 3 days/ week</p> <p>Treatment: Up to 40 minutes of treadmill walking</p>	<ol style="list-style-type: none"> Patients realized significant improvement in get up and return to sit time, straight away walk time, walking speed and cadence but not chair rise time. Stance duration and stance/swing ratio improved significantly on the paretic side but not the nonparetic side. Swing times did not improve significantly on either side symmetry data did not improve significantly. 	Case series Level IV (CEBM)
Smith et al (1999)	14 patients with "persistent gait deviations" (> 6 months post stroke)	<p>Duration: 3 months</p> <p>Frequency: 3 times/ week</p> <p>Treatment: Up to 40 minutes of treadmill walking.</p>	<ol style="list-style-type: none"> Concentric knee flexion torque increased significantly ($p < .01$) over time on the paretic and nonparetic sides. Eccentric knee flexion torque did not increase significantly over time. Reflexive torque generated by the hamstrings decreased significantly over time on the paretic side. 	Pre-post trial Level IV (CEBM)
Teixeira da Cunha, et al (2002)	13 acute rehabilitation patients: 7 regular intervention, 6 body weight supported treadmill training (BWSTT).	<p>Duration: Average = 3 weeks.</p> <p>Frequency: Daily</p> <p>Treatment: Three hours of physical therapy, with BWSTT substituted for usual gait training in BWSTT group.</p>	<ol style="list-style-type: none"> No significant difference between groups in changes in Functional Ambulation Category, speed, distance, energy expenditure, or metabolic cost. Effect sizes were medium to large for metabolic cost and distance. 	Randomized trial Level IIb (Greenhalgh)

<p>Teixeira da Cunha Filho et al (2001)</p>	<p>12 rehabilitation inpatients with significant gait limitation (< 6 weeks post stroke): 6 standard physical therapy, 6 standard physical therapy plus supported treadmill training</p>	<p><u>Duration:</u> Inpatient stay. <u>Frequency:</u> 5 days/ week. <u>Treatment:</u> 1 hour of regular physical therapy. 20 minutes of time was either regular gait training or body supported treadmill training.</p>	<p>1. No difference between groups in change in Functional Ambulation Category or Functional Independence Measure locomotion scores scores. 2. Maximum oxygen consumption (on bicycle ergometer) improved significantly more in treadmill training group.</p>	<p>Randomized trial Level IIb (Greenhault)</p>
<p>Visitin et al (1998)</p>	<p>79 rehabilitation inpatients: 43 body weight support, 36 no body weight support</p>	<p><u>Duration:</u> 6 weeks <u>Frequency:</u> 4 days/ week <u>Treatment:</u> Up to 20 minutes of treadmill training. All subjects wore harness, but subjects in the body weight support group had up to 40% of weight supported.</p>	<p>1. After controlling for pretraining status, post-training balance, motor recovery, and overground walking speed and endurance were significantly better in the BWS than in the NBWS group. 2. At 3-month follow-up, the BWS group still had better motor recovery and walking speed but not balance (p=.058) or walking endurance (p=.065).</p>	<p>Randomized trial Level IIa (Greenhault)</p>

Table 5. Results of Longitudinal Studies with an Emphasis on Gait Training via Treadmill

Study	Subjects	Intervention	Findings	Level of Evidence <i>Comments</i>
Glasser (1986)	20 patients (3-6 months poststroke): 10 additional Kinetron training, 10 control	Duration: 5 weeks Frequency: 5 days / week Treatment: Up to 30 minutes of daily training using the Kinetron	No significant difference in the improvement demonstrated by the two groups in Functional Ambulation Profile scores or ambulation time.	Randomized controlled trial Level IIb (Greenhough)
Hesse et al (2000)	2 nonambulatory (>2.5 months post stroke)	Duration: 4 weeks Frequency: 5 days/ week Treatment: 20 minutes on mechanized gait trainer	Both patients achieved independent walking with cane. Both demonstrated improvements in Rivermead motor assessment scores and gait speed (103% & 350%)	Pre-post trial Case series Level IV (CEBM)
Hesse et al (2001)	14 "severely gait disabled" (8 weeks-9 months poststroke)	Duration: 7 weeks Frequency: 5 days/ week Treatment: 3 weeks of 45 min of daily NDT approach physiotherapy and 4 weeks of 20 minutes of daily gait trainer in addition to baseline treatment.	Significant improvements occurred over the 4 week gait trainer period in: gait velocity, cadence, and stride length, Functional Ambulation Category scores, and Rivermead Gross Function and Leg and Trunk scores	Pre-post trial with baseline Level IV (CEBM)
Werner et al (2002)	30 nonambulatory patients (4-12 weeks poststroke): 15 beginning with gait trainer and 15 beginning with treadmill.	Duration: 2 weeks. Frequency: 5 days/ week Treatment: 15-20 minutes of body weight supported gait trainer or treadmill training	Functional Ambulation Category, gait velocity, and Rivermead Motor Assessment scores improved significantly over the course of treatment. 2. Improvements in the Functional Ambulation Category were greater in the gait trainer group. 3. Improvements in gait velocity and Rivermead Motor Assessment did not differ significantly between groups. 3. Spasticity did not change over time in either group.	Randomized ABA versus BAB trial Level IV (CEBM)

Table 6. Studies of Stepping Machines

Study	Subjects	Intervention	Findings	Level of Evidence <i>Comments</i>
Thaut et al (1997)	20 acute patients able to complete 5 strides with hand-held assistance by the therapist: 10 control, 10 rhythmic facilitation.	Duration: 6 weeks Frequency: twice daily Training: 30 minutes/ session Rhythmic facilitation= metronome or specially prepared music. Control= "same amount of time and distance with equivalent instructions regarding speed improvement."	Rhythmic facilitation resulted in significantly greater improvements in speed and stride length. Improvements in cadence and symmetry, though greater in the rhythmic facilitation group, were not significantly greater	Randomized controlled trial Level IIb (Greenhough)

Table 7. Longitudinal study of rhythmic entrainment

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FUNCTIONAL ELECTRICAL STIMULATION OF THE LOWER LIMB (R5)

The orthotic effect of functional electrical stimulation in stroke patients with a dropfoot: A systematic review

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ABSTRACT

Objective: Analysis of the available evidence of the effect of functional electrical stimulation of the dorsal flexors on walking in stroke patients with a dropped foot.

Methods: A systematic review was performed to identify trials that investigated the orthotic effect of FES on walking in stroke patients with a dropped foot. The primary outcome measures selected were walking speed and Physiological Cost Index (PCI).

Results: Eight studies were included in the review, of which two were randomised controlled trials. Six studies measured walking speed.

Conclusions: The present review indicates a positive orthotic effect of functional electrical stimulation on walking speed.

INTRODUCTION

Stroke is a major illness in Western countries with huge disabling consequences. The incidence of stroke in The Netherlands is approximately 30,000 per year and the prevalence is 120,000 patients¹. A stroke causes impairment of the cognitive, sensory, perceptive and motor functions. A common motor impairment is a dropped foot, which is characterised by the inability to dorsiflex the ankle, leading to insufficient toe clearance during walking. This impairment, in combination with commonly seen low selectivity of hip and knee motion in these patient group results in an abnormal gait, consisting of hip hitching, circumduction and toe catch, also called equine gait². As a consequence walking speed is impaired and there is a higher chance of stumbling and falling.

About 20% of the population with partial recovery have a dropfoot². Out of 120,000 stroke survivors 75% (90,000 patients) recovers only partially. This group of 90,000 includes approximately 18,000 patients with a dropped foot.

The conventional treatment of drop foot is a splint, usually a custom fitted ankle-foot orthosis (AFO), which is a plastic support worn inside the shoe to maintain the ankle joint in a neutral position, and occasionally a more substantial splint attached to the shoe. This treatment has limitations, being both uncomfortable and awkward to use³.

In 1961, a new method for correction of dropfoot by means of electrical stimulation was introduced by Liberson⁴. The stimulation was applied via electrodes on the skin and was synchronised with the gait phase by a heel-switch worn in the shoe. Stimulation was turned on when the heel was lifted at the beginning of the swing phase. It then produced dorsiflexion and eversion of the ankle joint. Stimulation was turned off when the heel was on the floor.

A number of (theoretical) advantages of FES in comparison to an orthosis can be mentioned. The active contraction of

the muscles stimulates the blood circulation, there is better afferent feedback, walking distance increases and the stimulator is cosmetically better accepted⁵. Furthermore Merletti mentions that walking with FES implies a more energy efficient use of the hip and knee muscles by avoiding the need for compensatory movements⁶.

However, the FES system is more sensitive to disturbance and, because of the placement of surface electrodes, the application requires more time.

FES is not appropriate for all stroke patients with a drop-foot. The patient has to be well motivated, able to stand and walk either alone or with minimal assistance and the muscles that raise the foot should not be denervated. Contraindications are communication disorders, irritation of the skin and limited range of movement. The use of FES is not widespread and the total number of patients being treated remains quite small. This can be attributed to several reasons, such as technical limitations and unfamiliarity with FES in many countries. Technical limitation occurred mostly with the use of surface stimulators and relate to items like lack of selectivity over the muscles and nerves recruited, high sensitivity of muscle recruitment to electrode placement and pain and tissue irritation associated with the passage of current through the skin⁷.

In order to improve selectivity of stimulation responses, implantable systems are developed^{7,8,9}. In contrast to the one-channel implantable stimulator, the two-channel stimulator provides separate control of the dorsiflexion and eversion movement by stimulating both deep and superficial peroneal nerves respectively. For more information about technical developments the reader is referred to a review of Lyons et al¹⁰. Preliminary trials have shown that it is possible to balance the foot well between inversion and eversion⁸. The principle aim of implantable systems is to establish an orthotic effect rather than producing motor relearning effects. When motor relearning is the main goal, surface stimulators are more indicated.

Although the concept of FES of the n. peroneus exists for more than 40 years, there is no hard evidence for the positive clinical effects of this treatment.

Glanz et al.¹¹ performed a meta-analysis to assess the efficacy of FES on paretic muscle force in the rehabilitation of stroke. They concluded that pooling from randomised trials supports FES as promoting recovery of muscle strength after stroke. A second review was carried out by Burrige et al.¹², who focussed on the orthotic and/or therapeutic effect of FES for the correction of dropped foot in subjects suffering from upper motor neuron lesions. However, their review had a descriptive character and study data were not pooled. Another aspect is that only surface stimulators to correct dropped foot were included. Their conclusion was that patients who benefit from FES, experience sufficient improvement in the speed and quality of walking to decrease dependence significantly.

The present systematic review was carried out to establish the available evidence of the orthotic effect of n. peroneus stimulation on walking speed. All types of stimulation approaches were included, i.e. surface, one- and two-channel implants. The orthotic effect is defined as the effect that occurs during stimulation while the therapeutic (carry-over) effect is the effect that remains even after the stimulator has been removed¹². The primary outcome measures selected from the present study are walking speed and Physiological Cost Index (PCI), which is a measure for energy cost.

METHODS

A literature search was performed in PubMed, in the Database of Abstracts of Reviews of Effectiveness (DARE), Cochrane database, NHS Economic Evaluation Database (NHS EED), and the Health Technology Assessment Database (HTA) from the NHS centre for Reviews and Dissemination of the University of York. The PubMed database includes literature from 1966 up to 2003. The following keywords were used separately and combined in PubMed: cerebrovascular accident, electric stimulation, electric stimulation therapy, rehabilitation, recovery of function, peroneal nerve, muscle spasticity, walking, comparative study, cost-benefit analysis and evaluation study. In the other databases, the previous terms and the following additional terms were used: dropfoot, dropped foot, ankle dorsiflexion, hemiplegia, FES, functional electric stimulation, peroneus and stroke.

Studies were included if they met the following criteria:

1. functional electrical stimulation of the peroneal nerve should be applied to stroke patients with a dropped foot to improve walking.
2. transcutaneous stimulators or implantable stimulators should have been used.
3. comparative trial design, comparing FES with either another treatment or baseline status.
4. studies examining an orthotic effect or both an orthotic and therapeutic effect.
5. full-length articles in English or Dutch language published between 1966 up to 2003.

A selection was made between clinical measures, i.e. walking speed, PCI and intermediate outcome measures, e.g. gait kinematics and spasticity. Walking speed at a self-selected pace and PCI were considered to be the primary outcome measures.

Finally all selected papers were rated and assigned a level of evidence and grouped into grades of recommendations as described by Shekelle et al¹³.

RESULTS

Selection of literature:

The systematic literature search in PubMed resulted in the identification of thirty articles. The search in the other databases did not yield additional articles. Twenty-two studies were excluded from this review. Reasons of exclu-

sion were that the study was not specifically about stroke patients^{14,15,16,17,18,19,20,21}, the study was not specifically about dropfoot^{11,22,23,24,25,26,27}, the study did not report on FES^{28,29} and the study was not a comparative trial^{3,30,31,32}. Two articles were about the same study and the second article did not yield additional information³³. The publications from Liberson, Buurke and Zilvold^{4,5,34} failed to meet the inclusion criteria that it should have been full-length publications written in Dutch or English between 1966 and 2003. Eight studies fulfilled the selection criteria and were included in the present review (Table 1)^{2,6,7,8,35,36,37,38}.

Characteristics of the included studies:

The number of patients included in the selected studies ranged from 2 to 56, with a total of 203 patients. In five studies chronic patients were included^{2,7,8,36,38}, in one study both chronic and subacute patients were included⁶ and in two studies chronic, subacute and acute patients were included^{35,37}. The first two weeks after the cerebro vascular accident is defined as the acute phase, the period between two weeks and 6 months after the accident is defined as the subacute phase and the period after 6 months is defined as the chronic phase. In total, 10 patients were in the acute stage, 17 patients in the subacute stage and 176 patients in the chronic stage after stroke.

Two of the studies were carried out in hospitalised patients^{35,38}. Three patients dropped out in two studies each^{37,38}. Of 203 patients, 101 were males, 44 were females and in 58 cases the gender was not mentioned. Paretic side was mentioned in six studies^{2,6,35,36,37,38}. Right hemiparesis was mentioned in 84 patients, left hemiparesis in 101 patients and in 18 cases the side was not mentioned.

Three different designs were used: two randomised controlled trials (RCT)^{2,35}, one cross-over study³⁷ and five times a within-subject comparison^{6,7,8,36,38}.

The method of FES varied between the studies. In five studies transcutaneous stimulation was used^{2,35,36,37,38} and in the other three studies implantable stimulation was applied^{6,7,8}.

In five studies, the patient could use the stimulator every day at home^{2,7,8,36,37}. In three studies this was not the case. In the study of Stefanovska patients had a limit of 2 hours/day to use the stimulator, Bogataj used treatment sessions of 30min-1h 5 days a week and the patients in the study of Merletti used the stimulator for 1-4 hours, 5 days/week. In the eight included studies a total of 20 different outcome measures were used. Walking speed was measured in six studies^{2,7,8,35,36,37} and PCI was measured in two studies^{2,36}. Merletti and Stefanovska both did not measure walking speed or PCI in their study.

In this review, walking speed and PCI are considered to be the primary clinical endpoints.

Table 1: Characteristics of included studies including the level of evidence

Effect of functional electrical stimulation on walking speed:

Table 2 shows the measured walking speeds with and with-

out FES and the difference between both measurements. It was not possible to calculate differences in walking speed for all studies due to insufficient data presentation^{8,36}. In three studies, a significant improvement in walking speed was found^{2,7,35}. Two other studies reported an improvement in walking speed as a percentage of difference without providing a measure of variability^{8,36} and the last study did not show a significant change³⁷.

Author	N	Level of evidence	Stimulator	Without FES (m/s) mean (SD)	With FES (m/s) mean (SD)	Difference (m/s) mean (SD)	Difference (%) (95% CI)
Waters (1975) ¹	16	IV	Implanted	0.58 (0.25)	0.79 (0.26)	0.21 (0.36)	36 (16.7-55.7)
Bogataj (1995) ²	20	IIa	Transcut.	0.21 (0.15)	0.35 (0.22)	0.14 (0.27)	67 (41.6-91.7)
Granat (1996) ³	16	III	Transcut.	0.89 (0.99)	0.93 (1.02)	0.04 (1.42)	4 (-68.8-77.7)
Burridge (1997a) ⁴	56	IV	Transcut.	-	-	-	14
Burridge (1997b) ⁵	32	IIa	Transcut.	0.68 (0.49)	0.77 (0.43)	0.09 (0.65)	13 (-14.7-41.1)
Kenney (2002) ⁶	2	VI	Implanted	-	-	-	27

Table 2: Walking speed

¹ before with orthosis, after with stimulation

² mean of cross-over, difference between treatment and control

³ mean of three surfaces, session 1 is used as before

⁴ after 3 months, difference between with and without stimulation

⁵ before FES group with stimulation, difference between treatment and control

⁶ mean of two subjects

Effect of functional electrical stimulation on Physiological Cost Index (PCI):

Two of eight studies, both carried out by Burridge, measured PCI^{2,36}. The first study showed a decrease of 39.5% in PCI, comparing PCI with and without stimulation after three months. There was no significant change in PCI over 3 months either with or without the stimulator. The second study, which was a RCT, showed an improvement of 24.9% in the FES group, when the stimulator was used, in a period of 12-13 weeks. Improvement was also measured in the control group with a reduction of 1% in PCI.

DISCUSSION

In the present review, the results of eight studies were analysed in order to assess the orthotic effect of FES on the improvement of walking in stroke patients with a dropped foot. Six of the eight studies measured walking speed and they suggest a positive effect of FES on walking. These studies, with exception of the study performed by Waters, made a comparison between walking with and without stimulation. Waters and associates made a comparison between walking speed preoperative with an orthosis and walking speed after surgery with stimulation. They found that walking speed increased significantly (37 percent) by applying FES.

In conclusion, FES seems to have a positive orthotic effect on walking speed, also when compared with the conventional treatment. The type of stimulator (i.e. transcutaneous or implanted) seems not to influence the walking speed.

For which patients:

Only 6 of 203 patients dropped out, which is quite remarkable. Two studies described that almost all patients continued to use the stimulator after the trial had ended^{2,36}. These findings could indicate that the use of the stimulator is not too difficult and patients are satisfied with the effects. Another explanation for this can be that the selection procedure of patients in the participating studies was successful. It is well known from the literature that 'FES' is a useful orthotic device for a selected sub-population of hemiplegic patients. According to Merletti and colleagues⁶ and Vodovnik³⁹, 20% of the ambulant hemiplegic population benefited from common peroneal stimulation during the rehabilitation period, but careful selection and application was important. Carnstam et al.¹⁴ found that careful selection led to a 94% success rate. Granat concludes that the stimulator applied in the late stage of rehabilitation would be applicable to a few patients (2%), particularly in patients with medio-lateral instability of the foot and reduced ground clearance in swing leading to forefoot

contact. According to Burridge² and Waters⁷ the stimulator does not work for everyone, although it was not mentioned to which criteria a patient should fulfil to be suitable.

Included studies:

Unfortunately, literature justifying the use of stimulation to correct dropped foot is mainly based on case studies, uncontrolled trials and retrospective reviews. In the present review two RCT's were included^{2,35}. Five of the eight included studies were open label studies, which means that there was no control group^{6,7,8,36,38}. The remaining study was a cross-over study³⁷, which design could be a problem in comparative trials using FES, because of a possible carry-over effect⁴⁰.

In this review, most of the patients (176/203) were in the chronic stage after stroke. The chance of spontaneous recovery in these patients is negligible so an observed effect can not easily be attributed to this. Therefore correction for natural recovery by randomisation seems not essential. Two studies measured not only chronic stroke patients, but also acute and subacute patients^{35,37}. Remarkable is the difference in walking speed measured before FES between both studies. The difference between Bogataj and Granat is 0.68 m/s or more than 4 times faster. Bogataj did not mention details about baseline measurements so the difference can not be explained by baseline measurement or selection procedure.

Burridge et al.² decided that a 10% improvement in walking speed was considered to be functionally relevant. In the present study, this improvement is reached by all studies, with exception of the study performed by Granat³⁷, who reached an improvement of only 4%.

Orthotic versus therapeutic benefit:

The present review focussed on the orthotic effect of FES on walking speed in stroke patients with a dropped foot. Another interesting aspect to consider is the possible therapeutic or carry-over effect of FES, which can be defined as the benefit gained following a period of stimulation. Liberson and associates noted that when footdrop was corrected in hemiplegic patients by means of electrical stimulation using cutaneous electrodes, some retained the ability to dorsiflex for varying lengths of time after stimulation was stopped⁴. Waters et al.⁸ observed the same phenomenon in some of their patients. They found an improvement in gait velocity without stimulation, compared with the velocity without an orthosis before surgery. The testing of these patients took place immediately after walking with stimulation. The review of Burridge et al.¹² also concluded that some studies^{14,41,42} reported a carry-over effect, which consisted of increased voluntary movement and reduced spasticity. It is unclear how this occurs, whether this effect is permanent, or how suitable patients can be identified. Many of the included studies were with small samples and few used convincing methodology.

Conventional treatment:

In the present review, only three of the eight studies included a control group^{2,35,37}. The control group in the study of Burridge² and Granat³⁷ both received physiotherapy. As only Granat described that during the control period the patients received their normal physiotherapy, it was not possible to examine if there was a difference in treatment intensity between both studies. The conventional treatment in the study of Bogataj³⁵ was much more comprehensive, consisting of physical therapy, medical treatment, occupational therapy, speech therapy, sessions with a psychologist, sessions with a social worker and a cultural program. These studies show that different conventional treatments exist with a large variation in intensity, which makes it difficult to compare their results.

CONCLUSION

FES seems to have a positive orthotic effect on walking speed and PCI. Walking speed also seems to increase when FES is compared with an AFO. In the literature it is not clear what proportion might benefit from FES. Future studies should report about suitability criteria for patients.

PCI is found to decrease in two studies^{2,36}. In one study, there was a significant decrease in PCI with and without stimulation after three months³⁶. No significant changes were found when comparing PCI before and after treatment. Although patients often reported that walking was less fatiguing, this seemed to be a psychological effect.

GRADE OF RECOMMENDATION

Recommendations are based on the level of evidence (listed in table 1 and 2) for each aim.

Aim:	Grade of recommendation
Effect of FES on walking speed	B
Effect of FES on Physiological Cost Index	B
Physiological Cost Index	

author	Waters (1975)	Merletti (1979)	Stefanovska (1988)	Bogatay (1995)	Granat (1996)	Burridge (1997a)	Burridge (1997b)	Kennedy (2002)
study design	before/with	before/with	before/with	experimental (RCT)	cross-over	with and without FES	experimental (RCT)	before/with
Patients								
number (dropout)	16	50 (3)	8	20	19 (3)	56	32	2 (0)
type	12/16 CVA	CVA	5/8 CVA	CVA	CVA	50/56 CVA	CVA	CVA
age (sd) [range]	49.3 (11.3)	57.3 (12.9)	45.4 (5.9)	56.3 (10.4)	57.8 (9.4)	54 (12)	56.8 (16.6)	[31-48]
stage after stroke	chronic	chronic	subacute + chronic	acute+subacute+chronic	acute+subacute+chronic	chronic	chronic	chronic
gender	8 male 8 female	36 male 14 female	7 male 1 female	11 male 9 female	16 male 3 female	not mentioned	23 male 9 female	not mentioned
paretic side	not mentioned	14 right 36 left	5 right 3 left	9 right 11 left	12 right, 7 left	27 right 29 left 1 bi	17 right 15 left	not mentioned
Intervention								
treatment	FES: implanted	FES: transcutaneous	FES: implanted	FES: transcutaneous	FES: transcutaneous	FES: transcutaneous	FES: transcutaneous	FES: implanted
control	no control group	no control group	no control group	conventional therapy	physiotherapy	no control group	physiotherapy	no control group
compared to	AFO	no aid	no aid	no aid	no aid	no aid	no aid	no aid
Training								
location	at home	hospital	at home	hospital	at home	at home	at home	at home
duration	6 months	1-9 weeks	6 months	3 weeks	4 weeks	3 months	12-13 weeks	20 weeks
intensity	daily, individually	5 days/week, mean 14 h	2 hours/day	5x/ week 30min-1h	daily, individually	daily, individually	daily, individually	daily, individually
Outcome measure								
clinical endpoint	walking speed	walking speed	walking speed	walking speed	walking speed	walking speed	walking speed	walking speed
other outcome	stride length	spasticity plantarflexors	max. isometr. torque:	distance	heel strike, inversion			endurance
	cadence, EMG	O2 consumption	dorsal/plantarflexion	number of strides, mean stride time	symmetry			isometric torque
Measurements		Kendall scale:	resistive torque pas. mov.	temporal symmetry,				
		dorsiflexion, eversion	every 6 mo	mean stance time, Fugl-Meyer		6 wks, 3 mo, every		
moments	every 3 mo	every 2 weeks	surf. stim. 30min/day,	every 3 weeks	0, 6 wks, 11 wks	6 mo	0, 4-5 wks, 12-13 wks	0, 32 wks
baseline	with+without orthosis	without aids	2-3 wks	not mentioned	usual aids	with and without FES	usual aids+FES	with/without usual aids
follow-up	with+without FES	with+without FES	without FES	after MFES+conv therapy	with+without FES	with and without FES	with+without FES	with FES
statistics	not mentioned	Student's t-test	not mentioned	MANOVA	ANOVA, paired t-test	paired t-test	Wilcoxon, Mann-Whitney	not mentioned
level of evidence	IV	IV	IV	Ila	III	IV	Ila	VI

Table 1 Characteristics of included studies

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PHARMACOLOGIC MANAGEMENT OF LOWER LIMB SPASTIC HYPERTONIA IN STROKE: WHAT IS THE EVIDENCE? (R6)

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INTRODUCTION

Spastic hypertonia of the lower limb muscles, along with its associated impairments, results in functional penalties, such as difficulty with transfers and gait. When severe, it may cause pain and lead to permanent contracture deformities. Recent investigations suggest that it may not be spasticity alone that causes these impairments and deficiencies in function.¹⁻⁵ Rather, the abnormalities associated with the upper motor neuron syndrome---dystonia, co-contraction of agonists and antagonists, clonus, weakness, incoordination-- are believed to play an important, if not predominant, role as well. Although the root of this problem has not been well established, therapeutic efforts have focused on peripheral (e.g., altering muscle properties through physical techniques) and central (e.g., influencing neurotransmission through GABA-mediated medications and modifying reciprocal inhibition through chemodenervation) strategies. When brought to the attention of a clinician, the impact of spastic hypertonia and its associated abnormalities on a stroke survivor's function and well-being are embodied by physical deformities and performance deficiencies. Thus, it is logical to direct treatment to not only what is believed to be the underlying pathologic phenomena at the central nervous system level, but also the resulting physical abnormalities. This explains why concurrent use of various treatment modalities (e.g., medications, orthosis, gait retraining) results in effective patient management.

The choice of treatment largely depends on the severity (i.e., the resultant physical deformities) and significance (the impact on an individual's abilities and well-being regardless of the severity) of spastic hypertonia. Although these are the most important determinants of treatment goals, other considerations include topographical involvement (i.e., focal vs generalized spastic hypertonia), disease etiology, previous response to therapies, ability to tolerate medication side effects, duration of disease, and cost. An astute clinician takes all these factors into consideration when designing a practical and effective treatment regimen for a stroke survivor affected by spastic hypertonia.

While it cannot be denied that there is a multitude of clinical successes of the various treatment modalities, there is little by way of evidence based on well-designed investigations to support them. In particular, there are only a handful of studies that were specifically intended to investigate the effectiveness of spastic hypertonia treatment of the lower limb after a stroke. This paper reviews these investigations and summarizes their findings. Recommendations for considerations for future studies are also made.

METHOD

Literature Search Strategy

A literature search using MEDLINE was used to identify all trials from 1967 to August 2003 that evaluated pharmacologic treatment of spastic hypertonia in stroke. Key

terms used were "stroke" and spasticity". In an effort to be exhaustive, both prospective and retrospective studies were considered, as were studies that used either an experimental or quasi-experimental design. Also considered were investigations that had different diagnostic populations enrolled in the same trial. Since double-blind, placebo-controlled trials were wanting, case series were also included, but not single case studies. Abstracts were not included either. Every effort was made to identify all articles in English that dealt with pharmacologic treatment of lower limb spastic hypertonia. Out of the 1,156 citations and abstracts assessed for suitability, 117 were considered for final review. This last evaluation resulted in the 27 studies used in the preparation of this report.

Quality Assessment

The organizing committee of the Consensus Conference on Orthotic Management of Stroke Patients, sponsored by the International Society for Prosthetics and Orthotics, decided to use a standardized system of review, following the guidelines referred to in the book, "How to Read a Paper- the Basics of Evidence Based Medicine".⁶

ORAL MEDICATIONS (TABLE 1)

Study Design and Methods

Only five studies⁷⁻¹¹ on oral spasmolytics were included in this review, since most of the abstracts on the spastic hypertonia management focused on the upper limb, and thus were excluded. All were double-blind and randomized, but only four were placebo-controlled, crossover investigations.^{7-9, 11} Two studies compared the efficacy of different medications (diazepam vs tizanidine; diazepam vs ketazolam vs placebo^{7,8}), while one¹⁰ looked at the effect of combining drugs (Dantrolene and diazepam vs each drug alone vs placebo).

Population

Not one of the studies was exclusive to stroke survivors, and none performed a separate analysis of the sub-population of stroke subjects. Thus, the results of the studies could not be generalized to the stroke population. Sample sizes were small (total 253, range 17-105), and the number of stroke participants in each study is even smaller, ranging from 9-89 (total 154).

Beyond the usual demographic data of subjects, some patient characteristics were not reported, such as ambulatory status, at study entry. Disease duration was not reported in any of the studies. Thus, improvement cannot be unequivocally attributed to treatment, since natural recovery may have played a role. Similarly, chronic complications, such as contractures, may have accounted for observed poor response to treatment in some.

Interventions

Doses of the medications used varied from study-to-study, but were all within the range of what is used clinically. None of the studies reported if the subjects received formal physiotherapy or other physical modalities.

Outcome Measures

Only one study¹¹ utilized a formal assessment tool for muscle hypertonia (Ashworth Scale)¹² in addition to goniometric measurements. The majority used subjective evaluation by the subjects, in addition to objective measures. In addition to the usual clinical measures, such as muscle strength assessment, clonus and spasm frequency, some employed electrophysiologic monitoring.^{7,10} None of these measures have been validated in the stroke population. Only the modified Ashworth score has been tested for reliability¹³ but its inter-rater reliability is in question.¹⁴

Like many studies on spastic hypertonia management in various patient populations, the most commonly used outcome measures assess impairment, instead of function. Only two investigations^{8,9} attempted to study the impact of treatment on ambulation. Moreover, the accompanying signs and symptoms of the upper motor neuron syndrome--co-contraction of agonist and antagonist muscle groups, incoordination---were largely ignored. (It must be pointed out, however, that the majority of the studies reviewed antedate the investigations that suggest the important role of these various deficits that co-exist with spastic hypertonia.)

Assessments were performed about every 1-2 wks, but the duration of follow-up assessment is short, since most studies were terminated after 8-12 weeks. The longest study was conducted over a 16 week period.¹¹ Thus, while some medications showed superiority over placebo in decreasing hypertonia and improving range of motion, the effects of long-term use of these medications are unknown.

Results

Diazepam, ketazolam, dantrolene, and tizanidine, were superior to placebo in various outcome measures. Table 1 summarizes the results of each study cited.

NERVE BLOCKS

Study Design and Methods

Only three studies¹⁵⁻¹⁷ on neurolysis for spasticity management were included in this review. One of the two case series reported the results of using etidocaine¹⁵ and the other,¹⁶ ethyl alcohol. The remaining study was a randomized trial comparing phenol 5% and botulinum toxin-A (Botox®) that claims to be a double-blind study.¹⁷ Strictly speaking, the patients were not blinded since there was a difference in the drug injection sites in the phenol and neurotoxin groups.

Population

Similar to studies on oral medications, investigations on nerve blocks had mixed diagnostic groups. Only one was composed entirely of stroke survivors.¹⁷ Disease duration was over 6 months in one,¹⁷ and ranged from 1-12 mo in

another.¹⁶ The remaining study¹⁵ did not report the interval between stroke onset and treatment. Sample sizes were small. All in all, there were a total of 32 stroke survivors out of a total of 42 subjects.

Intervention

One study used etidocaine 1%, 2 cm³ for femoral nerve block.¹⁵ Thus the effect of this treatment was only short-term due to the pharmacodynamic property of the drug. Chua and Kong¹⁶ used ethyl alcohol of varying concentrations (50-100%) to block the sciatic nerve. How different alcohol concentrations affected the study results could not be ascertained from the data reported.

The third study,¹⁷ compared tibial nerve block using phenol 5% with botulinum toxin-A 400 u distributed to the gastrocnemius, soleus, and tibialis posterior. However, the phenol group did not receive placebo injections in the three aforementioned muscles, and the vice-versa, the neurotoxin group did not receive placebo injection to the tibial nerve. Thus, a true double-blind condition did not exist. In spite of its limitations, the study is significant since thus far, it is the only comparative research of two different medications for injections.

Outcome Measures

All three studies used either the Ashworth Scale¹² or its modification¹³ as the primary measure. Other impairment measures used included range of motion, velocity of voluntary knee extension, and clonus duration. All three also gauged treatment effect on function (ambulation and brace wear). The phenol vs botulinum toxin study's final endpoint was at 12 weeks post-treatment,¹⁷ while the alcohol study,¹⁶ 6 months.

Results

Etidocaine nerve block of the femoral nerve resulted in reduction of quadriceps tone.¹⁵ Alcohol neurolysis of the sciatic nerve caused an improvement in modified Ashworth scores up to 6 months post-intervention, and in some subjects, improvement in ambulation quality and wheelchair positioning.¹⁶

While both phenol and botulinum toxin improved the Ashworth scores of ankle plantarflexors,¹⁷ it appeared that the toxin group had superior effects over phenol ($p < .05$) in improving muscle tone and decreasing clonus duration at 2 and 4 weeks, but not at 8 and 12 weeks, post-treatment. This is an interesting finding, since in most clinicians' experience, phenol is superior to botulinum toxin-A in decreasing clonus. Details of the results are summarized in table 2.

CHEMODENERVATION

Study Design and Methods

Six randomized, double-blind, placebo-controlled, parallel group trials and eight case series on botulinum toxin-A were reviewed. Only one case series on the use of botulinum toxin-B has been published.¹⁸ That study involved mixed diagnostic groups and investigated treatment effects only in the upper limbs. Thus, it was not included in this review. While most studies sought to demonstrate the efficacy of

botulinum toxin-A in spastic hypertonia with or without concurrent physiotherapy or use of electrical stimulation, one investigation's goal was to demonstrate a difference in treatment outcome depending on the site of injection within the gastrocnemius muscle.¹⁹

Population

Collectively, there were 459 stroke survivors among 552 subjects in all 16 studies. The six randomized, double-blind, placebo-controlled, parallel group trials accounted for 343 of stroke subjects. Only seven studies^{17, 20-25} exclusively studied stroke survivors. Disease duration varied widely within a single study. Onset of disease prior to intervention ranged from 3 months to 29.2 years. Since many studies with mixed diagnoses did not perform a separate analysis for the subset of stroke survivors, this data include those of subjects with other diagnoses. One study²⁶ did not report this information.

Similar to most spastic hypertonia interventional studies, the main entry criterion was impairment severity. Only four investigations²⁰⁻²³ explicitly reported that the stroke survivors' ambulatory status.

Intervention

Currently, botulinum toxin is manufactured and marketed either as Botox-A™ or Dysport®. Although both preparations are expressed in units, their potencies differ unit per unit. It is estimated that one unit of Botox® is equivalent to 3 to 4 units of Dysport®. While both are available in Europe, only the former is commercially available in the United States. Ten studies^{17, 19, 20, 24-29, 30} reviewed in this section utilized Botox-A™, while the remaining six,^{18, 22, 23, 31, 32} Dysport®. Botox-A™ doses ranged from 100 to 500 units, while Dysport® doses used in the studies ranged from 500 to 2000 units. One study³³ reported Dysport at doses ranging from 2.5 to 25 ng.

One report²⁵ investigated the therapeutic effect of Dysport® in conjunction with electrical stimulation, while another²² looked at the combined effects of Botox-A™, electrical stimulation and therapy. The latter study, however, did not specify the "dose" of therapy provided, i.e., the type, intensity, and daily duration of the physical intervention. Another study²⁰ allowed therapy following Botox® treatment, but limited exercise to no more than 30 min three times a week. One investigation²⁴ compared the outcome of a relatively high dose of Botox® with a lower dose plus ankle taping. A study¹⁷ comparing the efficacy of botulinum toxin with phenol nerve block, and was discussed in an earlier section.

Most studies used fixed doses of the toxin. Six²⁵⁻²⁹ allowed use of different doses. One Dysport study²³ compared three different doses of the drug to placebo. While some studies allowed injection of various muscles,^{24-26, 28, 29} invariably all trials involved the injection of the gastrocnemius. Other commonly injected muscles were the soleus and tibialis posterior. Details of the study methods and intervention groups are in table 3.

Outcome Measures

Once again, the primary outcome measure of most studies is the Ashworth scale or its modified form. Only two studies^{22, 23} used gait as the primary assessment measure. Several other studies used ambulation---chiefly, gait velocity--- as a secondary measure.

Except for one report²⁹ involving evaluation of the long-term effects (up to 2 years) of repeated toxin injections, the studies were limited to one-time treatment only. Post-treatment assessment in most studies was performed between 4 and 12 weeks. One³⁰ had a follow-up at 120 days post-injection and another up to 6 months post-treatment,²⁶ a time period that goes beyond the usual duration of effect of botulinum toxin-A in many clinical settings.

Results

All the studies showed that botulinum toxin, whether Botox-A™ or Dysport®, is effective in decreasing spastic hypertonia, and in certain subjects, improving gait speed. Interestingly, it appears that adjunctive electrical stimulation²¹ and ankle taping enhance the effects of botulinum toxin, and that botulinum toxin may improve the outcome of physiotherapy.²²

Many of the studies included subjects with various diagnoses, but a separate analysis for the stroke subset was not carried out. Therefore, results included those of subjects with other disease etiologies. Details of study results are found in table 3.

INTRATHECAL THERAPIES

Study Design and Methods

Four studies were considered for review.³⁴⁻³⁷ Two were randomized, double-blind, placebo-controlled, crossover trials,^{34, 37} and the other two,^{36, 37} case series. It must be pointed out that the former (both studies^{34, 35} being from the same investigation group) employed the randomized, double-blind, placebo-controlled, crossover design only in one phase of the study (intrathecal baclofen bolus injection during the screening trial), and then assumed an open-label design.^{34, 35}

Population

Collectively, 38 stroke survivors were studied in the four reports. One study investigated the use of continuous intrathecal infusion of baclofen in three stroke survivors out of six subjects. The subsequent studies restricted enrollment to stroke (both hemorrhagic and non-hemorrhagic) survivors only. Disease duration ranged from six months to 14 years prior at study entry. The ambulatory status of subjects in two studies were not reported.^{34, 35} In the two other investigations, only ambulatory subjects were enrolled.^{36, 37} In one,³⁶ the level of ambulation capabilities was further categorized based on Perry's classification.³⁸

Intervention

Thus far, baclofen is the only medication used in studies investigating the effects of intrathecal therapies in stroke-related spastic hypertonia. Elsewhere in the literature, medications, such as clonidine,³⁹ morphine,^{40, 41} and fentanyl,⁴²

have been reported in the spinal cord population. In the randomized, controlled studies,^{34,35} the effects of both single intrathecal baclofen bolus and continuous intrathecal infusion of baclofen via an implanted pump were assessed. One of the two case series³⁷ investigated only the effects of a single bolus intrathecal injection of baclofen, while the other,³⁶ continuous intrathecal infusion of baclofen via an implanted pump. At the end-point of the three studies on continuous infusion,³⁴⁻³⁶ the dosages ranged from 205.3 to 268 $\mu\text{g}/\text{day}$.

Although some studies acknowledged that the patients received physiotherapy after pump implantation, the frequency, intensity and type of physiotherapy were not reported.

Outcome Measures

In the two randomized trials^{34, 35} and in one case series,³⁷ the Ashworth score was the main outcome measure. In the former, reflex and spasm frequency scores were also reported, as were observations of functional improvement. One case series³⁶ utilized ambulation speed as the primary outcome measure.

Apart from reporting the impact on related impairments, such as clonus, the other phenomena that accompany spastic hypertonia, such as agonist-antagonist co-contraction and reduction of motor control and coordination, were not systematically measured, although in one study³⁶ their treatment impact is suspected to be responsible, at least in part, in the improvement in ambulation.

The longest follow-up duration in the studies was up to 25 months,³⁶ although the subjects in that study had varied follow-up periods. In one of the randomized trials, the end-point was at 12 months.³⁵

Results

All four studies³⁴⁻³⁷ reported decrease in spastic hypertonia, and other related impairments. Additionally, the two studies that specifically investigated the effects of intrathecal baclofen on function found an improvement in gait speed and other ambulation parameters. Details of the study results are outlined in table 4.

SUMMARY AND RECOMMENDATIONS

The majority of studies reviewed were at level of evidence VI (case reports). All in all, three studies^{11,23,32} were at level of evidence IIa; six,^{7-9,28,34,35} IIb; six,^{10,17,19,21,22,24} III; one,²⁰ V; and eleven,^{15,16,26,27,29,30-33,36,37} VI. When Grade of Recommendation based on Shekelle, et al,⁴³ is applied, none of the pharmacologic option received a grade A recommendation. The evidence for oral medications merited a grade of B, on the strength of level IIa evidence of the handful of studies. The preponderance of case series among studies involving phenol and alcohol neurolysis, botulinum toxin-A chemodenervation, and intrathecal baclofen therapy make them fall in the Grade C recommendation level.

Study Design and Method

As compared to upper extremity treatment, studies on lower limb management of spastic hypertonia are fewer in number. Some studies included both the upper and lower

limbs, and did not perform a separate analysis. Only a handful of these investigations were designed as randomized, controlled trials (RCT), the so-called "gold standard" of clinical studies. While it is tempting to recommend that more studies utilizing this design should be conducted in the future, one must consider its limitations. While RCT have a strong internal validity, its external validity is diminished by its use of stringent enrollment criteria and treatment protocols. Doing so assumes that all subjects have the same characteristics. In reality, subjects who present with lower limb spasticity have varying types, degree, and duration of deformities. They also have different goals (improve perineal hygiene vs facilitate wearing of orthosis vs improve gait). Strict inclusion/exclusion criteria and the use of a pre-set treatment algorithm (thus, ignoring the unique needs of a specific individual) limit the generalizability of results of RCT studies, since they do not reflect actual clinical practice. Useful complements to RCT trials are observational studies involving a large number of individuals, which is more representative of patients with a specific condition. This design is less restrictive than RCT trials, and does not exclude many conditions frequently encountered in clinical practice. Observational studies also have limitations, especially in terms of their inability to infer causality on the basis of observed associations.

Regarding the pathophysiology of spastic hypertonia, an important question that needs to be answered is, "*Is spastic hypertonia solely responsible for deformities and functional penalties, or are other phenomena contributing to the problem?*" Being able to clearly define the impact of spastic hypertonia and the other accompanying deficits (i.e., co-contraction of agonist and antagonist muscle groups, weakness, incoordination, loss of motor control) will help design studies that will employ accurate outcome measures and render appropriate treatment. Currently, the assumption is that spastic hypertonia, a velocity-dependent abnormal increase in muscle tone, is the chief etiology of the condition to be treated. Yet, the most commonly used measure to assess muscle tone, the Ashworth Scale,¹² does not hint at the status of the other spastic hypertonia-related phenomena. In this respect, the Tardieu scale may be a better alternative, because it considers the velocity of joint movement. However, it also has limitations, since it is not a practical measure for certain muscles (e.g., toe flexors), and its inter-rater reliability in stroke patients has not yet been investigated.

A recent study¹⁴ demonstrated poor inter-rater reliability of the Ashworth Scale, except when the score is 0 (no muscle tone abnormality). The other commonly used outcome measures, such as the spasm frequency score and global impression scales, have not been validated in this patient population.

Most studies use measures of tone impairment (e.g. Ashworth Scale) as the primary outcome measure. However, one must bear in mind that patients do not complain of these impairments, but instead seek help to improve function. A statistically significant decrease in Ashworth scores has no value to stroke survivors unless it translates to an improvement in the ability to walk or use the hand.

Laboratory assessment tools, such as electrophysiologic monitoring or motion analysis, provide a more objective measure, but they are not readily available to most clinicians. Thus, there is a need to develop clinical outcome measures that are simple to administer, valid, and has good intra- and inter-rater reliability. They should also be ecologically valid, i.e., the outcomes measured actually have an impact on real-life situations.

Patient Selection

In order to make better sense of treatment outcomes, future studies should report subject characteristics more clearly. Several factors may influence a person's response to a specific therapy. For instance, severity of spastic hypertonia, disease duration, functional capabilities and potential, and patient motivation, all play a role in therapeutic outcome. Disease duration is an important consideration. If enrolled too early in the recovery process, a good treatment outcome, e.g., enhancement of function, may not be due to the intervention, but rather, to natural recovery. Conversely, when a subject is enrolled many years after the onset of stroke and spastic hypertonia, the failure to demonstrate a positive change may not be due to non-response to treatment, but rather, to co-morbidities, such as contractures. Learned non-use of the limbs⁴⁴ over time may also account for failure to achieve functional progress after an intervention. The studies reviewed cannot answer the question, "How early should drug treatment be rendered?" This is an important issue, since many spasmolytic drugs have potential negative effects on cognitive recovery due to their effects on the GABAergic and alpha-adrenergic systems⁴⁵, and muscle paralysis. Hence, the "risk-benefit" ratio of any therapy should always be considered. An ideal way to study this is by comparing the short- and long-term efficacy and safety of an intervention in two comparable groups of stroke subjects, one receiving "early", and the other, "delayed" treatment.

Many studies enrolled mixed diagnostic groups. Future studies should limit enrollment to only one diagnosis, in order to make the results generalizable to a specific patient population.

Intervention

There are only a few trials on oral medications in the last few years^{11, 46} perhaps because these drugs are not well-tolerated by many stroke survivors, due to their sedating and drowsiness-inducing properties. However, for those who are able to overcome these adverse effects, certain medications may be helpful in alleviating spastic hypertonia, but their efficacy compared to other treatment options have not yet been evaluated. Perhaps, it is due time that an oral medication be compared head-to-head with either botulinum toxin or intrathecal baclofen therapies.

Botulinum toxin therapy has revolutionized the management of spastic hypertonia, because it provided a safe and effective alternative to oral medications. However, it appears to work best only when spastic hypertonia is focal, i.e. and limited to only a few muscles. Hundreds of articles on botulinum toxin-A for spastic hypertonia have

been published in the last few years, but only a few of them utilized an experimental design. It has been widely used clinically, yet answers to some questions are yet to be known: *What is the optimum dose of botulinum toxin for a specific muscle at a certain degree of spastic hypertonia? Does dilution of the toxin impact result? Is it really better than phenol, as suggested by one study?*¹⁷ *What is the role of adjunctive physiotherapy and physical modalities in enhance treatment outcome?*

In clinical practice, many patients receive physiotherapy following pharmacologic intervention, regardless of what drug was used. Hence the role of physiotherapy—both traditional methods, such as serial casting, stretching, and strengthening, and more contemporary strategies, such as constraint-induce movement therapy⁴⁷ and partial weight treadmill training⁴⁸—need to be elucidated further.

There are only a handful of studies on dosing, and it appears that higher doses of the toxin result in a more robust muscle tone reduction. However, this information is limited to only a few muscles, such as the elbow flexors, wrist and finger flexors, and ankle plantarflexors, which are most frequently studied. The doses used for other muscles are largely empiric, and based on a clinician's opinion and experience.

Many studies only look at the effect of botulinum toxin on only one or two muscles. If functional improvement is an intended outcome, then other muscle groups must be studied, as well. For instance, many lower limb studies focus on the ankle plantarflexors solely. Spastic hemiplegic gait is due not only to abnormalities around the ankle joint, but also to muscle weakness or muscle hypertonia in the knee and hip regions. Thus, a failure to demonstrate functional improvement is likely to occur, because not all abnormal muscle groups were treated. This is a typical scenario when strict treatment protocols are used in studies, where only a certain dose can be injected in pre-determined muscles. An attractive alternative is to investigate the effect of treatment when all abnormal muscles are injected. Doing so allows for a better assessment of treatment impact on function, but one must recognize its limitation, in that a non-standardized intervention was used.

Lastly, studies looking at the effect of combination therapies should be done in order to determine if this approach is more effective and less costly than monotherapy. It is common clinical practice to combine certain interventions. For example, those with severe spastic hypertonia may benefit from intrathecal baclofen therapy to manage the lower limbs, yet may need either phenol or botulinum toxin for certain muscles in the upper limb or should girdle. In other situations, some may benefit from a combination of phenol and botulinum toxin therapy for the treatment of proximal and distal spastic muscles, respectively, in the same limb. Some patients also benefit from receiving oral medications for sustained control of hypertonia, but may need an additional botulinum toxin injection to one muscle recalcitrant to the drug, or may not be able to tolerate adverse effects associated with further drug dose increases. These treatment approaches, while used widely, are yet to be subjected to formal studies.

In summary, while a significant advancement has been made in investigating the effects of various pharmacologic agents for lower limb spastic hypertonia in stroke, there is still a multitude of opportunities for studying the true clinical impact of these treatment modalities. Future studies should not be limited to interventional investigations only.

Further studies on the pathophysiology of spastic hypertonia and its associated impairments, the development of valid and reliable assessment measures, and a shift of focus of treatment goals from reducing impairments to enhancing function, should complement interventional trials in order to make the results more meaningful and applicable in real life situations.

Author (year)	Study Design	Subjects and Intervention	Results	Level of Evidence
Basmajian (1984)	Randomized, double-blind, placebo-controlled, crossover	24 stroke survivors out of 50 subjects, but only 19 completed study 3 treatment conditions: Ketazolam 10 and 20 mg/d (1 wk each) Diazepam 5 and 10 mg/d (1 wk each) Placebo (2 wks)	Ketazolam and diazepam conditions better than placebo on most outcomes (p<.05) but no significant difference between ketazolam and diazepam*	Iib
Bes (1988)	Randomized, double-blind, Parallel group	N=105 hemiplegics (89 stroke, 16 cranial trauma) 2 groups well-matched for sex, age, height and body weight: Tizanidine (46 stroke) started at 6 mg/d and titrated up to maximum of 24 mg/d within 2 wks (mean dosage at week 8: 17.08 mg/d); Diazepam (43 stroke) started at 7.5 mg/d and titrated up to maximum of 30 mg/d (mean dosage at week 8: 19.52 mg/d)	15 subjects on tizanidine and 6 on diazepam dropped out due to side effects* Tizanidine group improved walking distance on flat ground; 3 of 11 bedridden subjects on tizanidine, and 2 of 4 bedridden subjects on diazepam became ambulatory	Iib
Cocchiarella (1967)	Randomized, double-blind, placebo-controlled, multiple crossover	Mixed diagnoses; 16 stroke survivors out of 19, but were not identified in data analysis 5 treatment conditions: Placebo Diazepam 6 mg/d Diazepam 15 mg/d Phenobarbital 45 mg/d Phenobarbital 90 mg/d	No significant difference in leg drop and straight leg raise tests, and total steps taken* Slower ambulation while on diazepam 15 mg/d compared to placebo	Iib
Glass (1974)	Double-blind, placebo-controlled, crossover	24 stroke survivors out of 62; 16/62 participated in crossover phase, but only 11/16 completed (Unknown number of stroke survivors in crossover phase or among drop-outs) 4 Treatment conditions: Dantrolene (100 mg qid) Diazepam (5mg qid) Dantrolene (100 mg qid) and Diazepam (5 mg qid) Placebo	Combined dantrolene and diazepam was superior to diazepam or dantrolene alone or placebo in clinical measures*	III
Meythaler (2001)	Randomized, double-blind, placebo-controlled, crossover	9 stroke survivors among 17 subjects 2 Treatment conditions: Placebo; Tizanidine 4 mg qHS titrated to goal of 12-36 mg/d	Only 6 tolerated up to 9 pills of tizanidine (36 mg/d), while 11 tolerated all 9 placebo pills * Somnolence in 41% on tizanidine and none in placebo	Iia

Table 1. Oral Medications

Author (year)	Study Design	Subjects and Intervention	Results	Level of Evidence
Albert (2002)	Case series	7 stroke survivors out of 12 subjects with hemiplegia disabled by quadriceps overactivity Etidocaine 1%, 2 cm ³ was injected to block the branch of the femoral nerve to either the vastus intermedius or lateralis.	Decrease in quadriceps spasticity, but results were difficult to interpret, based on the data reported*	VI
Chua (2000)	Case series	5 stroke survivors out of 8 subjects with hemiplegia and severe knee flexor spasticity Ethyl alcohol 50-100% (with 1% lidocaine) injected to sciatic nerve using repetitive monopolar electric stimulation	MAS scores of knee flexors improved significantly at 1 (p<.005), 3 (p<.01), and 6 (p<.02) months post-injection*	VI
Kirazli (1998)	Randomized, double-blind (?), parallel group	N=20; Botulinum toxin-A (Botox®) 400 units injected to lower limb muscles using electromyographic guidance vs phenol 5% tibial nerve block	Significant improvement in AS in both groups (p<.05) for ankle plantarflexor; Toxin group had more improvement in AS of ankle invertors than phenol (p>.05); AS and clonus duration more improved in toxin group than phenol at weeks 2 and 4, but not at wks 8 and 12	III

Table 2. Phenol, Alcohol and Anesthetic Nerve Blocks

Author (year)	Study Design	Subjects and Intervention	Results	Level of Evidence
Dengler (1992)	Retrospective, case series	3 stroke survivors among 10 subjects, who received Dysport® 2.5-25 ng (mean 23.5 ng)	Improved AS(7/10) and ROM (4/6) ; Decreased Pain (4/4)*	V
Hesse (1994)	Case series	12 stroke survivors received 400 units Botox® to gastrocnemius, soleus and tibialis posterior plus therapy (no more than 30 min sessions 3 times/wk)	AS, stride length, stance, and swing symmetry significantly improved	V
Hesse (1995)	Cohort study	10 stroke survivors whose gastrocnemius, soleus and tibialis posterior were injected with: Group A: 2000 U Dysport® plus therapy Group B: 1500-2000 U Dysport® plus electrical stimulation and therapy	MAS, stride length, stance, swing symmetry, and gait velocity significantly better in Group B	III
Dunne (1995)	Case series	19 stroke survivors among 40 subjects, who were injected with Botox® to either the upper (mean dose 175 u, range 70-270) or lower limb (various lower limb muscles ; mean dose 221 u, range 100-500u)	Results difficult to interpret because of mixed diagnosis and different limbs. Also had different follow-up times. Reported improvement in MAS, pain, ROM, and function*	VI
Burbaud (1996)	Randomized, double-blind, placebo-controlled, parallel group	19 stroke survivors out of 23 who received either placebo or 1000 U Dysport® to lower limb muscles plus therapy	MAS, Fugl-Meyer and Subjective reports were significantly improved, while gait velocity showed trend toward improvement*	Ila

Pierson (1996)	Retrospective, case series	18 stroke survivors among 39 subjects; 17 of 39 subjects had lower limb Botox® injections	Improved AS, ROM, brace wear tolerance; Gait velocity improved by about 14%; Pain: 10/13 improved*	VI
Childers (1996)	Randomized, double-blind, placebo-controlled, parallel group	12 stroke survivors out of 17 subjects who received Botox® 50 unit in the gastrocnemius: Group A: injected proximally in a site near the muscle origin Group B: injected distally at 3 sites along the mid-belly	MAS improved in Group B at wk 4; No statistically significant difference in outcome between the 2 groups*	III
Reiter (1998)	Randomized, single blind, parallel group	18 stroke survivors; Group A: Botox® 190-320 u to various lower limb muscles Group B: Botox® 100 u plus ankle taping	MAS improved in both groups at 1 month ROM and Timed Ambulation improved in both groups	III
Viriyavejakul (1998)	Case series	22 stroke survivors received repeated injections of Botox® either in the upper and/or lower limb (100-150 u)	AS improved by 1-1.5 points. Improvement in Fugl-Meyer scores and subjective assessment. Increased ROM and decreased pain	VI
Kirazli (1998)	Randomized, double-blind (?), parallel group	20 stroke survivors; Botulinum toxin-A (Botox®) 400 units injected to lower limb muscles vs phenol 5% tibial nerve block	Significant improvement in AS in both groups ($p < .05$) for ankle plantarflexor; Toxin group had more improvement in AS of ankle invertors than phenol ($p > .05$); AS and clonus duration more improved in toxin group than phenol at weeks 2 and 4, but not at wks 8 and 12	III
Richardson (2001)	Randomized, double-blind, placebo-controlled, parallel group	23 stroke survivors among 52 subjects who received either placebo or Botox® 300-500 u to the upper and lower extremities, followed by therapy	AS improved in both groups, but more in Botox® group: ROM increased in Botox® group; Timed ambulation and nine-hole peg test unchanged; Goal attainment improved for both; Rivermead scores and subject problem ratings better lower limb function in Botox® group*	IIb
Suputtitada (2001)	Case series	14 stroke survivors among 20 subjects who received Botox® in the toe flexors or great toe extensor. Those with AS score of 2 received 25 u, AS=3, 50 u, and AS=4, 75 u	Improvement in all outcome measures. Most benefited up to 5-6 mo, while some, up to 2 yr*	VI
Johnson (2002)	Randomized, parallel group	21 stroke survivors unable to achieve heel strike that can be corrected by electrical stimulation were assigned to one of 2 groups to receive: Group A: physiotherapy only Group B: Physiotherapy plus Dysport® (200 u to each of the 2 heads of the gastrocnemius, and 400 u to the tibialis posterior). Some received functional electrical stimulation (FES)	Upward trend in both groups in median walking speed (Group A: $p = .02$; Group B: $p = .042$) Dysport® and FES in addition to physiotherapy appear to have beneficial effect on the outcome measures	III

Yelnik (2003)	Case series	11 stroke survivors with disabling overactivity of great toe extensor received Botox® 66-100 u	Decreased muscle overactivity and pain and improved shoe wear up to 3 mo	VI
Yelnik (2003)	Case series	Three stroke survivors with limited ROM and pain in shoulder received Dysport® 250 u to subscapularis	Improved Rom and decreased pain	VI
Pittock (2003)	Randomized, double-blind, placebo-controlled, parallel group	234 ambulatory stroke survivors injected with Dysport® in the gastrocnemius and soleus (without EMG guidance), randomized to the following groups: A: Dysport® 500 u B: Dysport® 1000 u C: Dysport® 1500 u D: Placebo	Significant increase (p<.05) in 2-min walking distance and stepping rate. Small but significant (p=.0002- .0188) improvement in MAS, pain, and reduction in use of walking aids	Ila

Table 3. Botulinum Toxin

Author (year)	Study Design	Subjects and Intervention	Results	Level of Evidence
Meythaler (1999)	Randomized, double-blind, placebo-controlled, crossover (screening phase), then, open label after ITB pump implantation	3 stroke survivors out of 6 with spastic hemiplegia	Average ITB pump dose 205.3 µg/d; Statistically significant improvement in average lower limb AS (p<.0001), reflex scores (p=.0208), and in average upper limb AS (p=.0002); No change in strength in non-hemiplegic side*	Iib
Meythaler (2001)	Randomized, double-blind, placebo-controlled, crossover (screening phase), then, open label after ITB pump implantation	21 stroke survivors	6 hr post-bolus injection: Statistically significant improvement in average lower and upper limb AS (p<.0001), lower limb reflex (p,.0001) and spasm (p<.0224), and in average upper limb reflex (p<.0004); Up to 12 mo post-ITB pump implantation (average dose 268 µg/d): Statistically significant improvement in average lower and upper limb AS (p<.0001) and lower limb reflex (p<.0001) scores; No change in strength in non-hemiplegic side; 3 subjects who were wheelchair-dependent became ambulatory with an assistive device after ITB pump implantation	Iib
Francisco (2003)	Case series	10 ambulatory stroke survivors	Statistically significant improvement after ITB pump implantation and physical therapy in MAS, walking speed, and functional mobility rating scores (p<.05); Normal muscle strength was preserved on non-hemiplegic side	VI
Remy-Neris (2003)	Case series	4 stroke survivors among 7 subjects with spastic hemiplegia involving quadriceps and triceps surae; Bolus intrathecal baclofen injection only	Significant improvement of Ashworth scores (p<.05) and maximal walking speed (p<.05); Preferred walking speed was unchanged; Minimal knee extension and maximal ankle flexion were the only kinematic data that significantly improved (p<.05); Comment: Results were based on entire sample and not on stroke subjects only	VI

Table 4. Intrathecal Baclofen (ITB)

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SURGERY FOR STROKE IN THE LOWER LIMB (R7-A)

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SUMMARY OF THE REVIEWED LITERATURE

The title of our Key review was "Surgery in the lower limb after stroke".

In the review we considered all published papers obtained by reference retrieval on RACAL and MEDLINE, and also by enquiry through the Royal College of Surgeons of England library using, initially, a search on the words, stroke, lower limbs, and surgery. Later a few further additions were submitted by Professor Mary-Ann Keenan from Philadelphia, USA. She suggested widening of the trawl by including neuro-orthopaedic treatments and upper motor neurone syndrome in the search.

After considering our own limited experience of performing surgery on CVA patients (in spite of the authors' combined extensive surgical practice in rehabilitation and orthopaedic surgery) we were unsurprised to find only 22 articles published in the English language literature.

As Key reviewers we discussed this closely, looking for possible reasons for the few published articles on CVA and surgery. Our principle conclusion was that there are few published articles of any worth, because internationally and nationally, there are few units that have dedicated surgeons on the rehabilitation team that looks after CVA survivors. The paucity of literature evidence appears to us to be related to the lack of a defined input from the surgical fraternity. This in effect means, we believe, that the medical and rehabilitation fraternity never (or hardly ever) refer chronic stroke victims for surgical opinions. This was confirmed to us by Professor T S Olsen (personal communication) speaking with authority from the Stroke Unit of Hvidovre University Hospital, Denmark at the Consensus Conference.

We wondered if this was because of surgeon disinterest, medical or rehabilitationist disinterest (or disfavour), ignorance (on all sides) or lack of opportunity. We could find no research question or published article on this subject anywhere.

Original 'Expert Opinion' papers (level of Evidence VII) make the point that in cases of spasticity after stroke there are deformities that develop because of the unopposed excessive muscle tone (the spasticity) – and these need not be structural, ie. dynamic deformity. The other main group of deformities occur after a time period, when such unopposed excess muscle tone exists, that collagen and fibrous tissue is laid down within and around the spastic muscles and in the adjacent joint causing structural change (eg. Mooney V & Goodman F 1969¹ and Waters RL, et al 1978²).

It is surprising to us that these important and seminal articles have not created the interest in the surgical world to allow more active treatment to occur since the 'aims' of good surgical practice are well known. We would have expected protocols to be published as to which stroke

patients should have operations or be considered for surgery – and which should not. In the preamble to most of the published articles that we have read there do appear statements suggesting that no patient should have surgery until 6 weeks after the CVA ; (and there are opinions given which put the figure much later than this) - no agreement based on evidence on timing for operation can be found in the literature. The fitness of the patients (we believe, but cannot be sure since no figures are published) is of importance. Vogt JC in 1998³ wrote about performance of the operations at the ankle mainly under local anaesthetic in his bedridden (sick) group. But this and all other papers found are all level V (level of evidence). Little description is offered of other assessment criteria, other than most patients appeared to be walking (? with or without aids) and were not demented or in 'severe' cardiac or renal failure, uncontrolled hypertension etc. Patient motivation was mentioned by some authors as being important in pre and post operation assessments but no assessment measures can be found by us to allow effective comparisons of patient or intervention situations.

The aim of any surgical operation on the lower limbs in stroke, is, we believe to alter the limb deformity after its' evaluation by clinical and other assessment. The latter includes, we think, a minimum of extensive naked eye observation with the patient supine standing and walking backed up, (in our opinion) by gait analysis.

If this technological approach is followed, we believe that clinical acumen can be augmented by the performance of a static or dynamic EMG recordings to establish which muscles are contracting (ie. are active or are silent) in the gait cycle (eg. Pinzur et al 1986)⁴.

He showed how EMG could be used for more accurate planning of surgery. Modern investigators can reproduce Pinzur et al's⁴ work in order to accurately decide if an active muscle is discovered on EMG, what time it is firing in the gait cycle when tested. His results show activity to be 'in-phase' or out of phase. Clearly a firing active/functional muscle will produce a greater malevolent influence on the gait pattern, if it contracts at the wrong moment in the gait cycle. Tibialis anterior, for example, is commonly 'on' in swing and stance phase after stroke. If so, then a varus deformity is common. None of the earlier articles on stroke surgery from other centres (not associated with Rancho Los Amigos Hospital, Los Angeles workplace of Dr Perry) consider this rather important neurophysiological investigative route as a guide to surgical treatment. Possibly the need for such investigations has not been appreciated by surgeons who have tried various operations, leading to a loss of enthusiasm for the techniques by patients, carers and their doctors.

All papers on surgical treatment imply or actually state that the aim of surgery procedures is to provide a plantigrade foot for the patient. This would clearly be a safe base of

support for the affected limb. The most obvious problems in stroke patients is at the foot/ankle, where equino-varus deformity is a common finding. Although surgical procedures can be performed to overcome the stroke stiff-knee walk when (rarely) a constant EMG discharge to the rectus femoris muscle is noted ; or when hip/knee flexion contractures are seen to be interfering with gait (and can thus be changed by operation) – the commonest treatable deformity remains the equino-varus difficulty at the distal limb.

In the Japanese culture, of communal bathing together with the removal of footwear at the entrance door to a dwelling, the continual application of AFOs to treat this equino-varus is a difficult problem for the stroke sufferer. He or she may be opposed to the wearing of a splint within the home. Several Japanese orthopaedic surgeons have therefore tried to alter the spastic equino-varus lower limb segment in order to discard (or lessen) patient walking dependence on orthoses. The objective appears to have worked for Ono (1980)⁵, Morita (1994,98)^{6,7}, Yamatomo (1992)⁸ and Takahashi (2002)⁹. All these authors claim improvement (or lessening) of orthotic need for their chronic stroke sufferers. Ono was the first to propose an anterior transplantation of the long toe flexors from the sole of the foot, bringing them to the foot dorsum, looping the tendons around the base of the 4th metatarsal (on the dorsal side). This procedure (combined with a posterior or postero-medial release) appears to produce a satisfactory outcome with up to 90% of patients apparently walking 'better' (not defined or measured by a validated method that was mentioned). The number of patients requiring less orthotic treatment post surgery appeared good, but there were no controls studied.

The most popular operation appears to be a SPLATT procedure (Split Anterior Tibial Tendon Transfer). This procedure is very well known surgically as an effective operation for fore and mid foot adduction/varus. The best article about it, in the context of stroke, is by Vogt (1998)³ which is only a level V paper. It nevertheless is of interest as the principles and techniques used for cerebral palsy spastic children are translated into post CVA spasticity management.

There are not even any attempts to control for the post-op surgical management, the operative techniques or what the subject characteristics were. Most papers do not mention what type of CVA had occurred (haemorrhagic or ischaemic); what the cognitive state of the patients were, and whether the degree of spasticity was measured by, for example, an Ashworth scale measure. In short, we are not told in any of the published articles whether there was any attempt to control for patient variability, the setting of the studies, the type of stroke or walking ability (before or after the intervention). All the articles are level V or less, except for one by Pinzur (in 1986)³ – in which a matched control series was treated (even so, with small numbers only). A few papers are identified as level IV – case control studies. Patient numbers in these studies are small. Nowhere did we find any RCT's, and there are no systematic reviews. There are no studies to prove the efficacy, or otherwise, of our given title, which was to consider the effects of surgery for lower limb problems in stroke.

The Level V papers mentioned are cross-sectional surveys or pre-post intervention studies or Case Reports. We consider that they all should be graded 'C' on the Shekelle scale grade of recommendation, no higher.

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Ranked and tabulated main references:

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1. Barnes et al	1991	IV/V
2. Botte MJ et al	1992	V
3. Close JR et al	1959	IV/V
4. Haslem et al	1964	VII
5. Keenan et al	1984	V
6. Keenan et al	1984	V
7. McCollough III NC	1975	V
8. Mooney V	1969	VII
9. Morita S et al	1994	IV/V
10. Morita S et al	1998	IV/V
11. Ono K et al	1980	V
12. Perry J et al	1966	VII
13. Perry et al	1978	V
14. Pinzur MS et al	1986	III/IV
15. Roper & King	1978	VI
16. Takahashi et al	2002	V
17. Tracey et al	1976	V
18. Vogt JC et al	1998	V
19. Waters et al	1978	V
20. Waters et al	1979	V
21. Waters et al	1982	IV/V
22. Yamamoto	1992	V

RELATED ARTICLES ABOUT SURGICAL TREATMENT FOR SPASTICITY IN OTHER CONDITIONS – Each marked with an asterisk *

- * Keenan, MA, Creighton, James; Garland, DE and Moore, Thomas: Surgical correction of spastic equinovarus deformity in the adult head trauma patient. *Foot and Ankle*, 5:35-41, 1984
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RECOMMENDED READING LIST, LOWER LIMB SURGERY FOR STROKE PATIENTS (R7-B)

Mary Ann E. Keenan, MD

SURGICAL TREATMENT OF LOWER EXTREMITY DEFORMITY OR DYSFUNCTION RESULTING FROM STROKE

Question #1: Current publications treat upper motor neuron syndromes as a group and do not single out those caused by stroke. Is it acceptable to review studies with mixed populations of patients with acquired upper motor neuron syndromes from central nervous system injury such as stroke and traumatic brain injury?

Waters, R. L., Frazier, J., Garland, D. E., Jordan, C., Perry, J. Electromyographic gait analysis before and after operative treatment for hemiplegic equinus and equinovarus deformity. 1982; *J Bone Joint Surg [Am]* 64; 284-8.

Level I

Prospective study of 27 hemiplegic stroke patients who underwent surgical correction of an equinovarus foot deformity. Surgical plan was based on dynamic EMG/Gait study done with a standardized protocol. All patients had post-operative gait study showing no change in the pattern of dynamic EMG activity.

Keenan MA, Creighton J, Garland DE, Moore T. Surgical correction of spastic equinovarus deformity in the adult head trauma patient. *Foot Ankle*. 1984;5(1):35-41.

Level III

Retrospective review of 59 consecutive traumatic brain injury patients who underwent surgical correction of an equinovarus foot deformity. Surgical plan based on dynamic EMG/Gait study done with a standardized protocol. Results compared with previous study of stroke patients. No difference seen in patterns of muscle activity between stroke and brain injured patients and same success rate for surgical outcomes.

Fuller DA, Keenan MA, Esquenazi A, Whyte J, Mayer NH, Fidler-Sheppard R. The impact of instrumented gait analysis on surgical planning: treatment of spastic equinovarus deformity of the foot and ankle *Foot Ankle Int*. 2002 Aug;23(8):738-43.

Level I

Department of Orthopaedic Surgery, Albert Einstein Medical Center, Philadelphia, PA

BACKGROUND:

Despite the logic behind instrumented gait analysis, its specific contribution to clinical and surgical decision making is not well known. Our purpose in this study was to determine the influence of gait analysis with dynamic electromyography upon surgical planning in patients with upper motor

neuron syndrome and gait dysfunction. **METHODS:** Two surgeons prospectively evaluated 36 consecutive adult patients with a spastic equinovarus deformity of the foot and ankle. After an initial history and physical exam, each surgeon independently formulated a surgical plan. Surgical treatment options for each individual muscle/tendon unit crossing the ankle included lengthening, transfer, release or no surgery. After the initial clinical evaluation and surgical planning, all patients then underwent instrumented gait analysis collecting kinetic, kinematic and poly-EMG data using a standard protocol by a single experienced physiatrist. Each surgeon reviewed the gait studies and patients independently and again formulated a surgical plan. The surgical plans were compared for each surgeon before and after gait study. The agreement between the two surgeon's surgical plans was also compared before and after gait study. Each patient was evaluated for the clinical outcome of surgery. **RESULTS:** Overall a change was made in 64% of the surgical plans after the gait study. The frequency of changing the surgical plan was not significantly different between the more and less experienced surgeons. The agreement between surgeons increased from 0.34 to 0.76 ($p=0.009$) after the gait study. The number of surgical procedures planned by each surgeon converged after the gait studies. Correction of the varus deformity was seen in all patients that underwent surgical treatment.

CONCLUSION:

Instrumented gait analysis alters surgical planning for patients with equinovarus deformity of the foot and ankle and can produce higher agreement between surgeons in surgical planning. **CLINICAL RELEVANCE:** The equinovarus deformity is due to a variety of deforming forces and a single, best operation does not exist to correct all equinovarus deformities. Rather, a muscle specific approach that identifies the deforming forces will produce the best outcomes when treating the spastic equinovarus deformity.

Iwaya T. [Electromyographic analysis of the leg muscles in the hemiplegic patients with equinovarus deformity of the foot] *Nippon Seikeigeka Gakkai Zasshi*. 1984 Oct;58(10):961-73. [Article in Japanese]

Level II

A series of EMG study of the leg muscles was carried out with a wire electrode in 86 hemiplegic patients of stroke to visualize the role of each muscle either in the development of equinovarus deformity of the foot or in correcting the deformity through tendon transfer. The muscles examined were anterior tibialis, posterior tibialis, gastrocnemius, soleus, flexor digitorum longus and peroneus brevis of the affected side. Tonic discharge of those muscles was recorded as the patients were elevating the affected leg in supine, sitting or standing posture or were standing on

legs. On lifting up the affected limb, most patients showed electrical activity of anterior tibialis with or without simultaneous activity of other muscles, most frequently with that of flexor digitorum longus or gastrocnemius. When the patient stood on legs electromyographic discharge appeared most frequently in soleus. Varus deformity of the foot significantly correlated to the lack of the electrical activity of peroneus brevis. Both such abnormal activity of anterior tibialis and the lack of activity of peroneus seemed to be the main causes for the varus deformity. Postoperative EMG study in the patients who underwent Watkins-Barr procedure of anterior transfer of the posterior tibialis tendon, showed that the posterior tibialis was rather inactive both in elevating the leg and in standing on legs. Varus deformity was corrected independent of the discharge of posterior tibialis. The author concluded that the correction of the varus deformity after Watkins-Barr procedure was mainly obtained from the tenodesis effect. The tenodesis provides the checkline effect on the equinus and varus deformity, which reinforces the dorsiflexing action of anterior tibialis and attenuates its inverting action of the same muscle.

ASSESSMENT:

- It is an acceptable practice to combine stroke and traumatic brain injured patient groups in research regarding the outcomes of surgical treatment of extremity deformities.
- Although it is common clinical practice to employ the same techniques of assessment and treatment for all patients with upper limb spasticity, there is no evidence to support including patients with childhood onset (cerebral palsy) of upper motor neuron disorders when evaluating treatments for stroke patients.

Question #2: Equinovarus foot is the most common lower extremity deformity seen following stroke. What is the evidence that supports surgical treatment of this problem.

Fuller DA, Keenan MA, Esquenazi A, Whyte J, Mayer NH, Fidler-Sheppard R. The impact of instrumented gait analysis on surgical planning: treatment of spastic equinovarus deformity of the foot and ankle Foot Ankle Int. 2002 Aug;23(8):738-43.

Level I – Prospective Study

Department of Orthopaedic Surgery, Albert Einstein Medical Center, Philadelphia, PA

BACKGROUND:

Despite the logic behind instrumented gait analysis, its specific contribution to clinical and surgical decision making is not well known. Our purpose in this study was to determine the influence of gait analysis with dynamic electromyography upon surgical planning in patients with upper motor neuron syndrome and gait dysfunction. **METHODS:** Two surgeons prospectively evaluated 36 consecutive adult patients with a spastic equinovarus deformity of the foot and ankle. After an initial history and physical exam, each

surgeon independently formulated a surgical plan. Surgical treatment options for each individual muscle/tendon unit crossing the ankle included lengthening, transfer, release or no surgery. After the initial clinical evaluation and surgical planning, all patients then underwent instrumented gait analysis collecting kinetic, kinematic and poly-EMG data using a standard protocol by a single experienced physiatrist. Each surgeon reviewed the gait studies and patients independently and again formulated a surgical plan. The surgical plans were compared for each surgeon before and after gait study. The agreement between the two surgeon's surgical plans was also compared before and after gait study. Each patient was evaluated for the clinical outcome of surgery. **RESULTS:** Overall a change was made in 64% of the surgical plans after the gait study. The frequency of changing the surgical plan was not significantly different between the more and less experienced surgeons. The agreement between surgeons increased from 0.34 to 0.76 ($p=0.009$) after the gait study. The number of surgical procedures planned by each surgeon converged after the gait studies. Correction of the varus deformity was seen in all patients that underwent surgical treatment.

CONCLUSION:

Instrumented gait analysis alters surgical planning for patients with equinovarus deformity of the foot and ankle and can produce higher agreement between surgeons in surgical planning. **CLINICAL RELEVANCE:** The equinovarus deformity is due to a variety of deforming forces and a single, best operation does not exist to correct all equinovarus deformities. Rather, a muscle specific approach that identifies the deforming forces will produce the best outcomes when treating the spastic equinovarus deformity.

Keenan, M. A., Lee, G. A., Tuckman, A. S. and Esquenazi, A. Improving calf muscle strength in patients with spastic equinovarus deformity by transfer of the long toe flexors to the Os calcis. J Head Trauma Rehabil 1999; 14: 163-75.

Level III – Retrospective Cohort Study

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The split tibialis anterior tendon transfer (SPLATT), Achilles tendon lengthening, and toe flexor release are proven and effective procedures for correcting a spastic equinovarus deformity of the foot. Paresis is a prominent feature of upper motoneuron syndrome. Lengthening the Achilles tendon, although necessary to correct the equinus, further weakens the gastrocnemius-soleus muscle group. The calf paresis commonly results in the need for an ankle-foot orthosis (AFO) during ambulation. Previous studies have shown that despite the correction of the equinovarus deformity, only one third of patients were able to ambulate without an AFO. The need for continued use of an AFO was because of insufficient calf strength to stabilize the tibia during late stance when the body mass is anterior to the ankle joint. This study prospectively evaluated the results

of transfer of the flexor hallucis longus (FHL) and flexor digitorum longus (FDL) to the os calcis in 30 patients. The transfer was done in an effort to augment the strength of the gastrocnemius-soleus muscle complex. Twenty-five patients in group I (the control group) underwent SPLATT, Achilles tendon lengthening, and toe flexor release. Thirty patients in group II (the study group) underwent the identical procedures plus the additional FHL and FDL transfer to the os calcis. Postoperatively, the varus and toe flexion deformities were corrected in all feet. In group II, two feet had a mild residual equinus that did not interfere with ambulation. Of the 11 patients who were not independent community ambulators in group I, 7 (64%) improved ambulatory status by at least one level after surgery. Of the 15 patients who were not independent community ambulators in group II, 14 (93%) improved ambulatory status by at least one level after surgery. In group I, 10 of 25 (40%) of the patients were brace free at follow-up. In group II, 21 of 30 (70%) were brace free at follow-up (c^2 , $P = .025$). These results indicate that the addition of an FHL and FDL transfer to the os calcis at the time of SPLATT, Achilles tendon lengthening, and toe flexor release improves calf strength and allows greater increase in function and less reliance on orthotics.

Morita S, Muneta T, Yamamoto H, Shinomiya K. Tendon transfer for equinovarus deformed foot caused by cerebrovascular disease. Clin Orthop. 1998 May;(350):166-73. Level IV – Case Series

Division of Rehabilitation Medicine, Tokyo Medical and Dental University, Japan.

Surgical correction was performed on 125 patients who had equinovarus deformity caused by a cerebrovascular accident and who needed an ankle foot orthosis for walking. The operative procedures involved anterior transfer of the long toe flexors (flexor hallucis longus and flexor digitorum longus; long toe flexor group) or lateral transfer of the anterior tibial tendon (anterior tibial tendon group), combined with lengthening of the Achilles tendon. On evaluation more than 2 years after surgery, 83 of 110 patients of the long toe flexor group and eight of 15 patients of the anterior tibial tendon group were able to walk without a brace. Five patients of the anterior tibial tendon group who had shown strong contraction of the anterior tibial muscle during the swing phase before surgery, needed a brace because of a drop foot after surgery. Thus, lateral transfer of the anterior tibial tendon was abandoned in 1984. Recurrence of varus deformity was seen in approximately 15% of the patients in both groups. Anterior transfer of the long toe flexors, using them as dorsiflexor tendons or for tenodesis, seemed to produce better results.

Vogt JC. Split anterior tibial transfer for spastic equinovarus foot deformity: retrospective study of 73 operated feet. J Foot Ankle Surg. 1998 Jan-Feb;37(1):2-7

Level IV – Case series

Clinique des Diaconesses, Strasbourg, France. The aim of this study was to describe the long-term results of split tibialis transfer in patients with stroke, cerebral palsy, and brain damage due to trauma, tumor, or infection. An evaluation was made of 73 feet in 69 patients with tendon transfer or lengthening for an average follow-up period of 44 months (range, 1 to 14 years). The primary indications for surgery included pain caused by pressure of the foot or toes on the floor or in shoes, ankle instability due to varus deformity, or difficulty wearing orthopedic shoes or braces. Chi(2) tests were used to compare preoperative and postoperative autonomy, and shoe and orthosis requirements. The results of this study include significant improvement in patient autonomy ($p < 0.001$), demonstrated by an improved ability to ambulate independently and a decreased need to wear orthopedic shoes ($p < 0.001$) and orthoses ($p < 0.001$), as well as an increased ability to wear normal shoes ($p < 0.001$). This procedure is safe and yields good results with minimal complications. The indications are very common, inasmuch as the number of young hemiplegic or tetraplegic patients surviving after a stroke or head injury is increasing. This procedure can result in definite improvement for these disabled patients and can increase their autonomy.

Lawrence SJ, Botte MJ. Management of the adult, spastic, equinovarus foot deformity. Foot Ankle Int. 1994 Jun;15(6):340-6.

Level V – Expert Opinion

Department of Orthopaedics, UCSD Medical Center 92103.

Management of the persistent, acquired, neurogenic equinovarus foot may be a confounding rehabilitative dilemma. Victims of cerebrovascular accidents and traumatic brain injury commonly develop this neurogenic deformity. The plantarflexed and inverted foot position results from an imbalance of forces about the hindfoot due to exaggerated muscle tone and hyperactive stretch reflexes. Significant functional impairment may ensue if a plantigrade foot position cannot be achieved and maintained. Surgical correction may be necessary if conservative measures fail. Determination of the dynamic and static components contributing to the equinovarus deformity is difficult. Gait analysis and dynamic electromyographic studies are valuable adjuncts for operative planning. The wide-ranging goals of surgery vary from improving transfer and ambulation skills, to assisting wheelchair positioning, to facilitating use of braces and/or shoe wear.

Edwards P, Hsu J. SPLATT combined with tendo achilles lengthening for spastic equinovarus in adults: results and predictors of surgical outcome. Foot Ankle. 1993 Jul-Aug;14(6):335-8.

Level IV – Case Series

West Virginia University, Morgantown 26506-9196. During a 4-year period, split anterior tibial tendon transfer (SPLATT) was performed on 42 adults with cerebrosplastic equinovarus deformity. Twenty-one patients (24 feet) had a minimum 1-year follow-up, which included detailed documentation of foot appearance position and function as well as ambulatory status. Thirteen patients were male and 8 were female. Average age of the patients was 41 years. Seventeen patients were independent ambulators with orthoses, one was a maximally assisted ambulator. Three patients with spastic quadriplegia were nonambulatory. All patients had uniform surgical technique and postoperative management. This paper presents the results of SPLATT and identifies risk factors for poor surgical outcomes. After an average follow-up of 39 months, 83% of the feet were rated as having good or excellent results. All ambulatory patients had improved gait and 35% of them were able to discontinue their orthoses. Poor surgical outcomes were associated with nonambulatory status in brain injured patients ($P = .018$). Salvage of failed SPLATT is discussed.

Pinzur MS, Sherman R, DiMonte-Levine P, Kett N, Trimble J. Adult-onset hemiplegia: changes in gait after muscle-balancing procedures to correct the equinus deformity. J Bone Joint Surg Am. 1986 Oct;68(8):1249-57.

Level IV - Case Series

Fifty-four adult patients with acquired spastic equinus and equinovarus deformity were treated with lengthening of the Achilles tendon, lateral transfer of the anterior tibial tendon, and appropriate muscle releases. All patients had preoperative dynamic electromyography and electrogoniometry performed in order to assist in planning the surgical procedures and to provide a baseline assessment of the dynamic deformities. Preoperatively, the stance and double-support phases of gait were prolonged. Throughout the stance phase, the gait of these patients was characterized by equinus deformity of the ankle, decreased flexion of the knee (hyperextension in the most severely involved patients), and increased flexion of the hip (which also varied with the severity of the equinus deformity of the ankle and hyperextension of the knee). In all patients, the operation was performed at least one year after onset of the hemiplegia. Clinical follow-up at an average of thirty months (range, twenty-four to sixty-two months) showed that the equinus deformity was corrected in all patients and that 59 per cent of them were brace-free. Two patients had a superficial infection that healed uneventfully, and two had pull-out of the tendon that required re-operation. Postoperative analyses of gait, performed at least one year after surgery for twenty-seven of the patients, showed that the stance and double-support phases of gait (which had

been prolonged before surgery) approached the findings in normal control subjects

Iwaya T. [Electromyographic analysis of the leg muscles in the hemiplegic patients with equinovarus deformity of the foot] Nippon Seikeigeka Gakkai Zasshi. 1984 Oct;58(10):961-73. [Article in Japanese]

Level II

A series of EMG study of the leg muscles was carried out with a wire electrode in 86 hemiplegic patients of stroke to visualize the role of each muscle either in the development of equinovarus deformity of the foot or in correcting the deformity through tendon transfer. The muscles examined were anterior tibialis, posterior tibialis, gastrocnemius, soleus, flexor digitorum longus and peroneus brevis of the affected side. Tonic discharge of those muscles was recorded as the patients were elevating the affected leg in supine, sitting or standing posture or were standing on legs. On lifting up the affected limb, most patients showed electrical activity of anterior tibialis with or without simultaneous activity of other muscles, most frequently with that of flexor digitorum longus or gastrocnemius. When the patient stood on legs electromyographic discharge appeared most frequently in soleus. Varus deformity of the foot significantly correlated to the lack of the electrical activity of peroneus brevis. Both such abnormal activity of anterior tibialis and the lack of activity of peroneus seemed to be the main causes for the varus deformity. Postoperative EMG study in the patients who underwent Watkins-Barr procedure of anterior transfer of the posterior tibialis tendon, showed that the posterior tibialis was rather inactive both in elevating the leg and in standing on legs. Varus deformity was corrected independent of the discharge of posterior tibialis. The author concluded that the correction of the varus deformity after Watkins-Barr procedure was mainly obtained from the tenodesis effect. The tenodesis provides the checkline effect on the equinus and varus deformity, which reinforces the dorsiflexing action of anterior tibialis and attenuates its inverting action of the same muscle.

Keenan MA, Creighton J, Garland DE, Moore T. Surgical correction of spastic equinovarus deformity in the adult head trauma patient. Foot Ankle. 1984 Jul-Aug;5(1):35-41.

Level III – Retrospective Cohort Study

Rancho Los Amigos Medical Center, Downey, California.

The results of 59 surgical procedures for correction of spastic equinovarus deformity of the foot using the split anterior tibial tendon (SPLATT) were reviewed in 54 adults with traumatic head injury. The mean time of follow-up was 49.7 months. Thirty-nine individuals had hemiplegic involvement, three had triplegic involvement, and 12 were quadriplegic. Evaluation of the patterns of lower extremity muscle activity preoperatively by dynamic electromyography in 33 patients showed no significant difference from that seen in the hemiplegic stroke population,

namely, spastic calf muscles with overactive toe flexors and anterior tibial muscle. At follow-up all feet were in a plantigrade position. The only complication was a superficial skin slough on the dorsum of the foot which healed uneventfully. Postoperatively, 18 extremities (31%) were brace-free. Forty-one extremities required support because of calf weakness, ataxia, or proprioceptive deficits. Of the 15 patients who were nonambulatory prior to surgery, nine (60%) became ambulatory. At follow-up 36 patients (67%) were independent ambulators, four (7%) required supervision assistance, two (4%) required standby assistance, and six (11%) required minimal assistance. The six individuals (11%) who remained maximally assisted or nonambulatory had improved wheelchair positioning and shoe wear. These results show that the split anterior tibial tendon transfer is a safe and effective procedure for the head trauma patient since it corrects the equinovarus deformity, allowing for improved shoe wear and wheelchair positioning in the nonambulatory individual and improved ambulation with decreased brace wear in the more functional patient.

Waters RL, Frazier J, Garland DE, Jordan C, Perry J. Electromyographic gait analysis before and after operative treatment for hemiplegic equinus and equinovarus deformity. J Bone Joint Surg Am. 1982 Feb;64(2):284-8.

Level I – Prospective Study

Rancho Los Amigos Medical Center, Downey, California.

Gait electromyograms were obtained before and after tendon transfer, lengthening, or release in twenty-seven hemiplegic patients with equinus or equinovarus deformities. Abnormal patterns of muscle activity almost always were present preoperatively in the gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, flexor digitorum longus, peroneus brevis, and tibialis anterior muscles in these patients. The surgical procedures to correct the foot deformities altered the gross patterns of activity of most of the muscles operated on by very little. Of particular importance to the surgeon was the finding that the pattern of activity of the muscles whose tendon was transferred, lengthened, or released was not altered after operation. This finding makes the preoperative gait electromyogram a useful means of determining the appropriate surgical plan, since it is an indication of the type of muscle activity to expect postoperatively.

Roper BA, Williams A, King JB. The surgical treatment of equinovarus deformity in adults with spasticity. J Bone Joint Surg Br. 1978 Nov;60-B(4):533-5.

Level V – Expert Opinion

Adults with deformities of the lower limb due to spasticity may be considerably improved by operation, but thorough pre-operative assessment as an inpatient is essential in order to pinpoint the disability. The commonest deformity is equinovarus which often responds to simple operative procedures. The results of seventy-seven operative procedures

in fifty patients are recorded. Correction once achieved is stable and the deformity does not recur.

Waters RL, Perry J, Garland D. Surgical correction of gait abnormalities following stroke. Clin Orthop. 1978 Mar-Apr;(131):54-63.

Level V – Expert Opinion

Rancho Los Amigos Medical Center, Downey, California.

Lower extremity abnormalities in stroke patients can be reliably improved by surgery. Surgical treatment is most frequently recommended for patients with: equinovarus; toe curling; excessive hip and knee flexion; limb scissoring. Unless the patient's disability is so severe he cannot walk, the operation is performed not before 6 and preferably not until 9 months after stroke.

Perry, J., Waters, R. L. and Perrin, T. Electromyographic analysis of equinovarus following stroke. Clin Orthop 1978;131: 47-53.

Level II - Development of diagnostic criteria on basis of consecutive patients

Rancho Los Amigos Medical Center, Downey, California.

The pattern of muscle activity was determined in 40 hemiplegic stroke patients with equinus, equinovarus or varus deformities. Although the exact pattern of muscle activity varied with each patient, the following general conclusions are possible. Premature firing of the triceps surae due to release of primitive locomotor control mechanisms and a hyperactive stretch response during limb loading are important causes of equinus. Prolonged firing of the tibialis anterior during stance and inactivity of the peroneus brevis are the principal factors responsible for varus.

Keenan, M. A., Gorai, A. P., Smith, C. W., Garland, D. E. Intrinsic toe flexion deformity following correction of spastic equinovarus deformity in adults. Foot Ankle 1987; 7(6): 333-7.

Level IV – Case Series

Adult Brain Injury Service; Rancho Los Amigos Medical Center, Downey, California.

In the treatment of spastic equinovarus foot deformities in adults with neurologic impairment, various surgical procedures are used including the split anterior tibialis tendon transfer and tendo achilles lengthening. Release of the flexor hallucis longus and flexor digitorum longus tendons in the midfoot is routinely included with these procedures to correct or prevent toe curling. In follow-up, residual toe curling has been observed in some patients despite release of the long toe flexor tendons. This study was undertaken to investigate this problem and its consequences, treatment, and treatment success. Forty-one feet in 34 consecutive patients were examined for residual toe curling an average of 2.5 years postoperatively. Thirty-two

feet (78%) were noted to have significant flexion deformities of the lesser toes. The residual toe curling caused pain in 72% of the feet and was associated with callosities on the dorsum of the toes in 59%. The incidence of residual toe curling secondary to spasticity of the flexor digitorum brevis and intrinsic muscles of the foot was similar in the patients who had sustained traumatic brain injury and in those who had suffered a cerebrovascular accident. Twelve of these feet (37%) underwent surgical release of the flexor digitorum brevis and intrinsic tendons to correct the toe curling. There were no complications of surgery and no recurrences of deformity following the surgery. A second surgical procedure to release the flexor digitorum brevis and intrinsic tendons to correct the toe curling was more commonly performed in the younger more active brain-injured patients than in the older stroke patients (44% versus 20%, respectively).

ASSESSMENT

- There is strong evidence supporting the surgical treatment of the spastic equinovarus foot deformity in the stroke patient.
- Preoperative assessment of the deformity with dynamic poly-electromyography allows for a more specific treatment plan of which muscles to lengthen or transfer.

Question #3 – What is the evidence regarding the causes and surgical treatment of the spastic planovalgus foot deformity?

Young S, Keenan MA, Stone LR. The treatment of spastic planovalgus foot deformity in the neurologically impaired adult. Foot Ankle. 1990 Jun;10(6):317-24.

Level IV – Case Series

Rancho Los Amigos Medical Center, Downey, California.

The surgical correction of 14 feet with spastic planovalgus in the neurologically impaired adult is reviewed. Evaluation of the patterns of lower extremity muscle activity preoperatively by dynamic EMG showed overactivity of the peroneus longus. A new gait pattern which has not been previously reported was observed. This “combination foot” deformity, noted in six patients, consists of equinovarus in swing, and planovalgus in stance during the gait cycle. The remaining eight patients exhibited planovalgus in swing and stance. Transfer of the peroneus longus tendon to either the cuboid or navicular was performed in seven (50%) patients. Release of the peroneus longus was performed in four (29%) patients. Two patients had Z-lengthening of the peroneus longus, and tenodesis of the peroneus longus to posterior tibialis was performed in one patient. The mean postoperative follow-up time was 34.6 months. All feet were plantigrade. Ten (71%) feet were balanced. Four (29%) feet were improved. There were no failures or complications. Thirteen patients were able to ambulate independently after surgery and one patient continued to

require only stand-by-assistance secondary to balance problems. No patient decreased in ambulation level. Seven (64%) of the 11 patients who required bracing, preoperatively became brace free. Peroneus longus was found to be the major deforming force in spastic planovalgus. Release, transfer, or tenodesis of the peroneus longus is effective in correcting planovalgus.

ASSESSMENT

- There is only one paper in the literature on this topic. More information is needed to elucidate the causes and treatment options of this deformity.

Question #4: What is the evidence supporting the surgical treatment of hip flexion, adduction or extension deformities in the stroke patient?

Ofluoglu D, Esquenazi A, Hirai B. Temporospacial parameters of gait after obturator neurolysis in patients with spasticity. Am J Phys Med Rehabil. 2003 Nov;82(11):832-6.

Level IV – Case Series

Department of Physical Medicine and Rehabilitation, Marmara University School of Medicine, Istanbul, Turkey.

OBJECTIVE:

The management of spasticity should be implemented with the most appropriate pharmacologic agents. Ideally, these agents should provide functional improvement with minimal adverse effects. The aim of this study was to evaluate the width of the base of support and the velocity of gait before and after obturator nerve block. Blocks were performed with aqueous phenol solution in patients with unilateral hip adductor muscle overactivity that resulted in scissoring gait. The goal was to analyze functional improvement and quantify outcomes and to attempt to document adverse effects. **DESIGN:** This retrospective study analyzed data from 24 patients' files. Inclusion criteria included subjects whose main functional complaint was an adducted gait pattern. All subjects were able to consent for and to undergo unilateral obturator neurolysis with 7% phenol solution. Temporospacial parameters of gait were obtained using the Gait Mat II before and after obturator nerve injection. **RESULTS:** The analysis showed no statistical change in the walking velocity or step length. However, the width of the base of support was significantly increased after injection. No postblock complications were reported.

CONCLUSION:

Obturator neurolysis with 7% phenol solutions is an effective procedure to decrease hip adductor muscle overactivity without reported complications. In the studied population, improvement was found in the width of the base of support without immediate change in walking velocity or step length.

Gardner MJ, Ong BC, Liporace F, Koval KJ. Orthopedic issues after cerebrovascular accident. Am J Orthop. 2002 Oct;31(10):559-68.

Level V – Expert Opinion, Review paper

Medical College of Pennsylvania, and Hahnemann University School of Medicine, Philadelphia, USA. Patients who have had a cerebrovascular accident with resultant hemiplegia often present to the orthopedic surgeon with characteristic complaints and deformities. The most common of these include muscle spasticity and contracture, shoulder pain, hip fracture, and heterotopic ossification. Although some of these disorders are clinically evident, others may be easily overlooked. The purpose of this article is to summarize the most common orthopedic aspects of hemiplegic patients who have had a cerebrovascular accident.

Botte, M.J., Waters, R.L., Keenan, M.A.E., Jordan, C., Garland, D.E.: Orthopaedic management of the stroke patient: Part II: Treating deformities of the upper and lower extremities. *Orthopaedic Review* 27:891-910, 1988.

Level V –

Expert Opinion, Review Paper

Kozin, S.H.; Keenan, M.A.E.: Principles of Surgery for Adult Brain Injury. *Current Orthopaedics*. 5:75-83, 1991.

Level V –

Expert Opinion, Review Paper

Anmuth, C.; Esquenazi, A., and Keenan, M.A.E.: Lower extremity surgery for the spastic patient. In *SPASTICITY*, Katz, R. (ed.), Physical Medicine and Rehabilitation: State of the Art Reviews 8(3), 547-564, 1994.

Level V –

Expert Opinion, Review Paper

Fuller, D.A.: Keenan, M.A.; Esquenazi, A.: Neuro-Orthopaedic Surgery for Lower Extremity Dysfunction in Upper Motor Neuron Syndrome. *Europa Medico Physica* 4: 1999.

Level V –

Expert Opinion, Review Paper

Keenan, M.A., Esquenazi, A. and Mayer, N.H.: Surgical Treatment of Common Patterns of Lower Limb Deformities Resulting from Upper Motoneuron Syndrome. *Adv Neurol*. 87: 333 -346, 2001.

Level V –

Expert Opinion, Review Paper

ASSESSMENT:

- Although there are review papers and textbook chapters that describe the surgical treatment of hip adduction, flexion or extension contractures in stroke patients, there are no published results of these treatments. **Question #5: What is the evidence supporting the surgical treatment of knee flexion deformity?**

Laborde A, Caillet F, Eyssette M, Boisson D. [3D preliminary analysis gait in stroke patients: knee flexion in compensatory strategies] Ann Readapt Med Phys. 2003 Apr;46(3):132-7.

Level II

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OBJECTIVE:

The aim of this preliminary study was to assess strategies of walking a stride in stroke patients with spastic right hemiplegia.

MATERIAL AND METHODS:

Gait was recorded in 3D in seven patients without other locomotion disorders. Kinematics data were studied only on the sagittal plane. The position and trajectory markers on the right side were studied during the swing phase in comparison with static standing position. Results were confronted with angular data.

RESULTS:

Three walking models were defined: 1) near normal gait with normal mobility in the knee; 2) gait with hicking while the flexion of the knee was reduced; 3) gait with a "talus" foot without motor recovery necessitating a pendular movement.

DISCUSSION:

The second pathological group was characterized with insufficient flexion in the knee in lifting the foot from the floor. In this group, patients adopted a compensation strategy with hicking in making the stride without touching the floor. We raised the question of limiting this adaptive strategy in order to enhance their remaining mobility.

CONCLUSION:

A 3D strategy gait analysis, before therapeutic choices, seems to confirm the value of analysing kinematic data in stroke patients with hemiplegia. The amplitude of knee mobility and hip compensation strategy can be specifically studied to improve the effectiveness of therapeutic strategies (orthosis, selective tibial neurotomy, botulinum toxin).

Keenan MA, Ure K, Smith CW, Jordan C. Hamstring release for knee flexion contracture in spastic adults. Clin Orthop. 1988 Nov;(236):221-6. Level IV – Case Series
Rancho Los Amigos Medical Center, Downey, California 90242.

Thirty adults (17 male and 13 female patients) with spastic disorders were treated by hamstring releases of 46 extremities. The diagnoses were stroke, traumatic brain injury, spinal cord injury, multiple sclerosis, and anoxia. The

mean age at surgery was 38.6 years. Three extremities had partial release of the hamstring tendons behind the knee; the remaining 43 extremities had a complete release. The average position of the knee was 61.4 degrees of flexion preoperatively and 6 degrees postoperatively. The follow-up period averaged 21.3 months. Preoperatively, 87% of patients were nonambulatory. Following hamstring release 43% became ambulatory and 17% had gained the ability to transfer. Complications included two stroke patients with severe peripheral vascular disease; one developed a large nonhealing sore of the ankle and the other developed gangrene of the foot. Both patients required amputation. Three other patients developed recurrent flexion contractures that have since been re-released with good results.

ASSESSMENT:

- Although it is common orthopaedic practice to treatment spastic knee flexion contractures, there is only case series describing the outcome of these procedures in adult patients.
- Additional studies are needed in this area.

What is the evidence supporting the surgical treatment of stiff knee gait?

Kerrigan DC, Karvosky ME, Riley PO. Spastic paretic stiff-legged gait: joint kinetics. Am J Phys Med Rehabil. 2001 Apr;80(4):244-9.

Level I

Department of Physical Medicine and Rehabilitation, Harvard Medical School, Boston, Massachusetts 02114, USA.

OBJECTIVE:

The authors previously suggested that spastic paretic stiff-legged gait, defined as reduced knee flexion in swing associated with upper-motor neuron injury, can be attributed to multiple impairments besides spastic quadriceps activity. This study hypothesizes that subjects with spastic paretic stiff-legged gait have altered kinetics not only about the knee but also about the hip and ankle. DESIGN: Joint kinetic data of 20 subjects with spastic paretic stiff-legged gait caused by stroke were compared with data obtained from 20 able-bodied subjects. RESULTS: Significant reductions in the subject group were found in both peak knee-joint power absorption (0.42 ± 0.34 vs. 0.99 ± 0.27 W/(kg x m x m/sec)) and peak ankle-joint power generation (0.74 ± 0.42 vs. 1.51 ± 0.17 W/(kg x m x m/sec); both $P < 0.0001$). The authors observed increases in peak external-hip flexion torque in stance, hip-power generation in loading response, knee-extension torque in midstance, ankle-dorsiflexion torque, and ankle-power absorption in stance. There was substantial variability in most torque and power values among subjects, which was significantly greater than that observed in the control subjects.

CONCLUSIONS:

These findings, in conjunction with previous studies, support the likelihood of multiple mechanisms for reduced knee flexion in swing. Alternatively, some of the joint kinetic differences could be compensations for or associated with reduced knee flexion in swing. The substantial variability among subjects implies that despite a similar visual appearance of reduced knee flexion among subjects with a spastic paretic stiff-legged gait pattern, each individual has unique mechanisms associated with this observed gait pattern.

Riley PO, Kerrigan DC. Kinetics of stiff-legged gait: induced acceleration analysis. IEEE Trans Rehabil Eng. 1999 Dec;7(4):420

Level I

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Treating spastic paretic stiff-legged gait, defined as reduced knee flexion in swing, holds a high priority in the rehabilitation of patients with upper motor neuron lesions. We propose a method to determine the relative contributions of hip, knee, and ankle impairments to this disability. We analyzed the gait of ten patients with stiff-legged gait (SLG) due to a single stroke and ten healthy, able-bodied controls. Using subject specific models, we analyzed the induced accelerations (IA's) at the knee. Knee IA's throughout the gait cycle were calculated and the sum of the IA's was compared to the knee joint angular acceleration estimated from kinematic data. The preswing and early swing IA's were the focus of our examination as these largely determine knee kinematics in swing. Knee angular accelerations estimated from IA's and kinematic data agreed for both controls and patients. Gait cycle IA analysis of individual patients identified highly variable causes of SLG including ankle and hip joint impairments. Induced acceleration analysis (IAA) suggested that multiple impairments, not just about the knee, but also about the hip and ankle, lead to this disability. Individual subjects are likely to have individual reasons for their stiff-legged gait. Defining the link between the patients specific impairments and their gait disability should be a goal of clinical gait analysis. IAA is a useful tool for this purpose with a strong potential for clinical application.

Kerrigan DC, Frates EP, Rogan S, Riley PO. Spastic paretic stiff-legged gait: biomechanics of the unaffected limb. Am J Phys Med Rehabil. 1999 Jul-Aug;78(4):354-60.

Level I

Department of Physical Medicine and Rehabilitation, Harvard Medical School, Spaulding Rehabilitation Hospital, Boston, Massachusetts 02114, USA.

A concern for individuals with hemiparesis affecting their gait, which heretofore has never been studied, is the possibility that various compensations occurring in the unaffected limb may strain or fatigue the muscles or ligaments and/or predispose to joint injury in that limb. We studied the biomechanics of the unaffected limb during walking in 20 subjects with hemiparesis who had stiff-legged gait as a result of stroke. An optoelectronic motion analysis and force platform system was used to estimate torques in all three planes about the hip, knee, and ankle. Sagittal plane joint motion and power about the unaffected hip, knee, and ankle were also studied. Data were compared with control walking data collected from 20 able-bodied controls. On average, peak torques and powers were all either reduced or the same compared with controls, even though in some instances values were >2 standard deviations (SD) above the control means. Our findings suggest that on average the probability of excessive muscular-tendon effort and the risk for biomechanical injury in the unaffected limb are minimal compared with able-bodied, walking controls. However, given individual variability, we recommend routine clinical gait analysis for all people with stiff-legged gait to eliminate excessive values in certain biomechanical parameters, which could, if not addressed, predispose to muscle-tendon strain or joint or ligamentous injury.

Casey Kerrigan D, S Roth R, Riley PO. The modeling of adult spastic paretic stiff-legged gait swing period based on actual kinematic data. *Gait Posture*. 1998 Mar 1;7(2):117-124.

Level I

Gait Laboratory, Department of Physical Medicine and Rehabilitation, Harvard Medical School, Spaulding Rehabilitation Hospital, 125 Nashua Street, Boston, MA 02114, USA

With the ultimate goal to better demonstrate the biomechanics of spastic paretic stiff-legged gait, we simulated the motion of this gait disability, based on actual kinematic gait data. We created and applied a seven link-segment forward dynamic model to the gait kinematics of five adult subjects with this gait disability as a result of stroke. Trunk and limb segment torques developed during the affected limb's swing period of gait were calculated via inverse dynamic techniques from the measured kinematic data and incorporated into the forward dynamic model to simulate motion. In each case, the simulated motion corresponded to the directly measured kinematics. The hip and knee torques were then altered to predict potential resultant changes in knee flexion. Preliminary results suggest a stronger effect of hip torque than knee torque on knee angle, which also qualitatively corresponded with clinical data. This study demonstrates the feasibility of forward dynamic modelling based on actual clinical data and provides a further means to analyze potential mechanisms of this gait disability.

Riley PO, Kerrigan DC. Torque action of two-joint muscles in the swing period of stiff-legged gait: a forward dynamic model analysis. *J Biomech*. 1998 Sep;31(9):835-40.

Level I

Department of Physical Medicine and Rehabilitation, Harvard Medical School, Spaulding Rehabilitation Hospital, Boston, MA 02114, USA. patriley@thelma.mgh.harvard.edu

Stiff-legged gait, characterized by limited knee flexion during the swing period, is a common consequence of upper motor neuron injury. The purpose of this investigation was to determine whether the rectus femoris and hamstrings muscles (which act at both the hip and knee) contribute to stiff-legged gait if active during the swing period of the gait cycle. Ten subjects with unilateral stiff-legged gait due to stroke were evaluated. Swing period free gait data were obtained. A biomechanical model of the affected limb was developed for each subject. Muscle and tendon lengths were scaled to individual subjects while constant nominal values for maximum muscle forces were used for all subjects. Torque driven forward dynamic simulations were employed to determine the sensitivity of swing period maximum knee flexion angle to changes in hip and knee torques. Combined torque and muscle driven simulations were used to access the action of specific two-joint muscles. Both hip flexion torque and knee extension torque were found to influence knee angle, but knee angle was more sensitive to changes in torque at the knee joint. The actions of the rectus femoris and long hamstrings are most marked at the knee, although their action at the hip opposes their action at the knee. Rectus femoris activity during early swing acts to limit knee flexion and contributes to stiff-legged gait. Long hamstring activity in early swing contributes to knee flexion.

Sung DH, Bang HJ. Motor branch block of the rectus femoris: its effectiveness in stiff-legged gait in spastic paresis. *Arch Phys Med Rehabil*. 2000 Jul;81(7):910-5.

Level IV

Department of Physical Medicine and Rehabilitation, Sungkyunkwan University School of Medicine, Samsung Medical Center, Seoul, Korea.

OBJECTIVE:

To verify the efficacy of motor branch block of the rectus femoris for stiff-legged gait in spastic patients. **DESIGN:** Before-after treatment trial. **SETTING:** University hospital physical medicine and rehabilitation department outpatient clinic. **PATIENTS:** Thirty-one adult spastic patients with stiff-legged gait. **INTERVENTION:** Motor branch block of the rectus femoris with 2% lidocaine and 5% phenol. **OUTCOME MEASURES:** Subjective assessment of gait performance by patients themselves and objective assessment of gait speed and sagittal knee kinematics. **RESULTS:** Seventy-four percent (23/31) of patients felt an improve-

ment (improved knee bending, disappeared toe dragging) after nerve block with lidocaine. Sixteen of 17 patients with an abnormal swing phase activity of the rectus femoris without that of the vastus medialis or lateralis and 20 of 23 patients with a sufficient hip flexor strength expressed an improvement subjectively. Gait analysis showed increased maximal knee flexion at swing phase and increased slope of knee flexion curve at toe off ($p < .05$). Phenol block was performed in 19 of 23 patients who had had a subjective improvement in their gait performance after nerve block with lidocaine. Gait speed, maximal knee flexion angle at swing phase, and slope of knee flexion curve at toe off increased significantly after phenol block ($p < .05$).

CONCLUSION:

Motor branch block of the rectus femoris can be an effective treatment in stiff-legged gait. Its effect is varied with hip flexor strength and dynamic electromyographic findings of quadriceps.

ASSESSMENT:

- A variety of papers exist evaluating stiff knee gait in both adults and children with spasticity. The deformity appears to be the result of a variety of factors including spasticity of the quadriceps muscles.
- Although there are multiple papers reporting the outcomes of surgical treatment of stiff knee gait in children with cerebral palsy, there were no articles found on the outcome of rectus transfer in adults.

RECOMMENDATIONS:

1. Surgical correction of limb deformities resulting from muscle imbalances after stroke is useful to improve both active and passive functions of the limb and the individual.

2. Dynamic poly-electromyography is essential to understand which muscles are responsible for the deformity or dysfunction observed. Dynamic poly-EMG should be performed before surgery when the goal is to improve the active function of the extremity. Dynamic EMG is not needed prior to the surgical correction of static limb contractures, which are being performed to improve passive function.

3. Upper motor neuron syndromes resulting from stroke and traumatic brain injury are sufficiently similar to the same allow the same approach for evaluation and treatment of limb deformities in both patient populations.

4. Surgical correction of a spastic equinovarus foot deformity is an established and effective treatment which provides permanent correction of the foot deformity. Correction of an equinovarus foot deformity leads to an improved base of support for standing, transfers and ambulation. Surgical correction of a spastic equinovarus foot deformity is also useful in non-ambulatory patients to improve or allow protective shoe wear and to improve sitting balance by providing a stable base for the feet.

5. A valgus foot deformity is not common in the stroke patient. The etiology of this deformity is not well established. There is only one paper published on the treatment of this deformity. Further studies are needed on this topic.

6. Hip flexion and adduction contractures are common in stroke patients. Although surgery is commonly done for these deformities, there are no published studies on the outcomes of surgical treatment. Studies are needed to establish the usefulness of surgery for hip deformities in the stroke patient.

7. Knee flexion deformities are common in stroke patients. Although surgery is commonly done for these deformities, there is only one published case series on the outcome of surgical treatment. Additional studies are needed to establish the usefulness of surgery for knee flexion deformities in the stroke patient.

8. The stiff knee gait is a very common problem for stroke patients. Much has been reported on the effectiveness of the rectus femoris to sartorius transfer for treatment of stiff knee gait in cerebral palsy patients. There are no published reports of this treatment in the stroke patient. Studies are needed to establish the usefulness of surgery for stiff knee gait in the stroke patient.

ORTHOTIC MANAGEMENT OF THE HIP AND KNEE FOR THE POST-CEREBROVASCULAR POPULATION (R8)

Deanna Fish, MS, CPO

INTRODUCTION

Cerebrovascular accident (CVA) accounts for a large percentage of rehabilitation cases worldwide. As many as 50% of new CVA patients present with little to no walking ability¹ during the early phases of their recovery and rehabilitation program. The confounding factors affecting walking ability include but are not limited to: flexor or extensor synergies, alterations in force generation and force regulation, muscle weakness, spasticity, sensory deficits, contracture formation, decreased range of motion, poor balance capabilities, decreased postural control, and asymmetrical movement patterns²⁻¹¹. Often irreversible loss of motor function combined with sustained and profound weakness prevents the recovery of an effective and efficient gait.

The purpose of orthotic rehabilitation is to enhance recovery, substitute for functional deficits, improve efficiency, and improve overall quality of life. It is common practice to 'wait and see' what the level of spontaneous recovery allows during the rehabilitation process. While overbracing can present negative outcomes by perhaps preventing or delaying the recovery of motor patterns, underbracing has just as severe consequences with the development of compensatory movements and postures^{1,12}. The orthotic challenge remains in the design of an effective lower extremity orthotic system that provides maximum stabilization of various joints during early walking efforts with adjustable components to address both stability and mobility issues throughout the gait training process when changes in individual strength and control appear. Finally, the orthotic rehabilitation program is completed with the provision of a minimal amount of functional assistance and structural support individualized to each patient profile.

PATIENT EVALUATION

Examination about the hip, knee and ankle involves the evaluation of muscle strengths and joint ranges of motion, as well as the identification of any contractures present. Stages of hypotonicity and hypertonicity are noted along with the sensory determination of touch, pinprick, vibration sense, and position sense⁵. In the absence of quantitative gait analysis, several members of the rehabilitation team may perform clinical observational gait assessment. All findings are coordinated and summarized as the basis for the initial rehabilitation program.

COMMON GAIT DEVIATIONS

Each patient must be evaluated thoroughly in order to fully assess and understand the dynamics of the gait pattern presented and to determine the most effective orthotic design available to enhance the walking abilities of each person. With CVA, abnormal control messages are sent from the brain resulting in hemiplegia of the contralateral side of the body. Paralysis, weakness, disrupted motor

control and spasticity create incoordination and dysfunction in upright posture and walking abilities¹³. The deviations may be a direct result of the neurological insult or may be the indirect result of a variety of compensations produced to address the specific task of walking. One of the greatest challenges for the rehabilitation professional is to distinguish the neurological consequences from the compensations in order to better direct rehabilitation efforts at the underlying causes of movement dysfunction during the early stages of recovery.

Hemiplegic gait does not consist of a single characteristic gait pattern but rather presents with many variations within the stroke population. Common characteristics include but are not limited to: asymmetrical stance, decreased weight transfer through the affected limb, disrupted swing and stance phase ratios, hypertonicity and extensor synergies, reduced walking speed, decreased functional ambulation capacity, poor balance, alterations to the muscular activity pattern of the lower limbs, and increased effort and energy costs^{4,5,10,13-17}. The degree and combination of various factors are unique to each patient's walking profile. Four different patterns of muscle activation in the paretic lower limb have been described¹⁸: 1) premature activation of the ankle plantarflexors usually combined with a decreased activation of the ankle dorsiflexors, 2) absence or marked decrease in two or more muscle groups, 3) coactivation of several muscle groups without a significant decrease in activation, and 4) complex activation not characterized by the other three patterns. Essentially, the variability in muscle activation patterns in the CVA population is high, and therefore the specifics of the resultant gait patterns are unique to the individual^{7,9,12,19}.

Primary knee and hip dysfunctions can be divided into stance and swing phase deviations, with applications to stability and mobility, respectively. It is impossible and impractical to consider the joints independently without recognizing and assessing the influence of proximal and distal joint alignments and motor control patterns, as well as the resultant effect on both the knee and hip during walking. Conversely, it is just as important to recognize the influence the knee and hip may have on proximal and distal alignments and compensations. The primary knee and hip dysfunctions will be outlined below and discussed in relation to orthotic management of each major joint during swing and stance phases.

PRIMARY KNEE DYSFUNCTIONS

Knee joint alignment in stance is very much influenced by the neuromuscular control and joint alignments of the foot and ankle in a closed kinetic chain. During swing, knee joint excursions are dramatically influenced by hip joint function and the dynamics of forward momentum. For the purposes of this paper, knee joint dysfunctions (and later hip joint dysfunctions) will be identified relative to the stance or

swing phase of gait, related to neurological consequences or functional compensations of the task requirements, and discussed relative to the influences of proximal and/or distal joint and mechanical alignments.

EVALUATING STANCE PHASE DYSFUNCTION OF THE KNEE – EXCESSIVE FLEXION

The knee joint presents with two dominant sagittal plane stance phase deviations – excessive flexion or excessive extension. The two deviations are not mutually exclusive and each may be noted at different phases of stance. Excessive flexion can affect all five phases of stand: initial contact, loading response, midstance, terminal stance and preswing. This excessive flexed posture of the lower limb results in decreased step length, excessive hip flexion and ankle dorsiflexion, ipsilateral pelvic drop, drop of the center of mass, ipsilateral and anterior trunk lean, difficulties with contralateral limb advancement in swing, loss of terminal stance stability, and shortened contralateral step^{12,20}. Swing phase is delayed and additional effort is required to lift the body mass up and over toward the contralateral stance limb.

Excessive knee flexion in stance results in the initiation of swing from a flexed posture that is neither efficient nor effective at translating the body mass forward in space. Essentially, the patient collapses onto the affected extremity, transfers a minimal amount of weight only long enough to allow the contralateral limb to rush through swing phase and make contact with the ground to prevent complete collapse. Excessive knee flexion may be the result of quadriceps weakness, shortened or uncoordinated quadriceps activity, gastrocnemius-soleus weakness, excessive dorsiflexion of the ankle, and/or hip flexion contracture^{10,20}.

Early knee flexion during loading produces significant limb instability and is most often seen during early periods of recovery when flaccidity and generalized lower extremity weakness are more pronounced²¹. Orthotic design should consider the application of an anterior dorsiflexion stop to substitute for the lost function of the posterior calf group. This anterior stop creates an anterior moment arm in front of the knee, encouraging knee extension as the body mass and thigh segment progress over the fixed base of support¹². Fine-tuning of the anterior stop is required to directly affect the initiation, duration and magnitude of the flexion resistance at the knee and to promote an effective and efficient gait pattern. This mechanical control can also have a significant effect on the proximal pelvic alignment during stance as well as the contralateral step length.

EVALUATING STANCE PHASE DYSFUNCTION OF THE KNEE – EXCESSIVE EXTENSION

Excessive knee extension is the more common sagittal plane knee joint deviation and as many as 40-68% of CVA patient suffer from knee hyperextension²². Hyperextension is often a component of an entire synergistic limb posturing and also disrupts the entire stance phase. Initial contact and loading response experience a disruption to forward momentum by the loss of knee flexion. Excessive plantarflexion of the ankle is noted distally. Excessive

hip flexion, pelvic retraction and anterior trunk lean occur proximally in an effort to move forward over the rigid and non-yielding lower limb. Preswing reveals the delay of an adequate hip flexion moment for swing. Loss of knee flexion in swing encourages compensatory movements such as circumduction or sound side vaulting.

The most obvious contralateral compensation is a step-to-gait pattern where the contralateral limb is advanced only up to the affected stance limb and not beyond due to the delay of forward progression of the body mass. Common causes of excessive knee extension during stance include: inadequate dorsiflexion range of motion at the ankle, spasticity of the ankle plantarflexors, plantarflexion contracture, spasticity of the quadriceps, ligamentous and/or capsular laxity at the knee, hip abductor weakness, and postural compensation for anterior knee instability^{3,21-24}. Lack of dorsiflexion range during stance creates a posterior force at the knee (i.e. hyperextension) and forces an anterior trunk lean (i.e. hip flexion) as the patient works to advance the body mass up and over the affected limb. In hypertonic conditions, the limb strikes the ground in a toe-heel manner, the body weight rapidly forces the heel to the floor, and a spastic triceps reflex is activated and forces the knee into hyperextension. Equinus of the foot/ankle complex combined with sustained extension or hyperextension of the knee disrupts terminal stance and preswing advancement of the lower limb segment over the base of support and prevents the development of an effective propulsive phase²¹.

EVALUATING STANCE PHASE DYSFUNCTION OF THE KNEE – COMBINED DEVIATIONS

Combined patterns may present with both excessive knee flexion and excessive knee extension during stance phase. Excessive flexion may be observed during initial contact and loading response followed by a posterior deviation of the knee at or around midstance. This deviation serves to disrupt forward momentum and places the posterior soft tissue structures of the knee at risk for permanent damage and deformation. Unaddressed, a patient walking with such a hyperextension moment is at risk to develop a permanent genu recurvatum deformity. Such deformation creates permanent damage to the cruciate, collateral and oblique popliteal ligaments, menisci, and posterior capsule of the affected knee^{8,22}. Genu recurvatum has been measured as high as 22 degrees¹⁸, contributes to increased energy costs, produces pain, and is considered to be a chronic deteriorating problem for a large portion of the stroke population.

EVALUATING SWING PHASE DYSFUNCTION OF THE KNEE – EXCESSIVE FLEXION

Sagittal plane deviations are again the most common swing phase deviations identified during observational gait assessment. Excessive knee flexion is usually secondary to excessive hip flexion, when a steppage gait is used to compensate for lack of dorsiflexion at the foot and ankle. In this pattern, excessive hip flexion produces excessive knee flexion during initial swing and midswing – an effective yet energy consumptive compensation for loss

of distal foot and ankle control. Excessive knee flexion evidenced in terminal swing will shorten the step length on the affected side and predispose the limb to excessive knee flexion during initial contact. Hamstring spasticity, decreased knee extension in early swing and knee flexion contracture has been identified as potential contributors to excessive knee flexion during swing^{21,26}.

EVALUATING SWING PHASE DYSFUNCTION OF THE KNEE – EXCESSIVE EXTENSION

Excessive extension of the knee during swing is most often identified with a stiff-knee gait and is accompanied by plantarflexion of the ankle. Lack of knee flexion at preswing increases the difficulty of initiating swing phase and forces compensations such as ipsilateral hip circumduction, contralateral trunk lean, posterior pelvic thrust, and/or contralateral vaulting in order to provide sufficient swing phase clearance for the affected limb^{21,26}. Terminal swing is reached with an extended knee, misaligned pelvis and shortened step length. Hyperextension as a result of high-velocity terminal extension is another possible cause of excessive knee extension in terminal swing⁴.

Multiple mechanisms of excessive knee extension in swing have been identified. These mechanisms include: increased activities of the quadriceps, incoordination or co-activation of the hamstrings, hamstring spasticity, lack of momentum, impaired hip flexion and impaired ankle control^{19,21,26,27}. Moore et al further detailed specific manifestations that decreased knee flexion during swing, specifically noting that "...the failure to flex the knee adequately in swing may lie in the inability to set up swing phase during stance²⁶". Riley and Kerrigan²⁸ evaluated the influence of two-joint muscles, specifically the rectus femoris and long hamstrings on knee range of motion during walking. These two muscles have opposite influences on flexion and extension at the hip and knee, and uncertainty remains as to the specific roles of coordination these two muscles perform in hemiplegic gait. As there is substantial variability in the neurological consequences and walking patterns, these mechanisms are not mutually exclusive and more than one may be responsible for the resultant excessive knee extension in swing.

ORTHOTIC MANAGEMENT OF THE KNEE

The implications of distal and proximal joint alignments and control have been noted to profoundly affect the knee, both in terms of stability and mobility. For the patient recovering from CVA, the knee joint is but one component of the affected lower limb and rarely is it indicated for the knee to be addressed independently. As such, knee control can be provided indirectly by control of the foot, ankle and shank of the affected limb or directly be control of the foot, ankle, shank, and thigh of the affected limb.

The sagittal plane kinematics of the knee can be addressed with an ankle-foot orthosis (AFO). AFOs are made from a variety of plastic and metal materials utilizing a number of different mechanical ankle joints to substitute for or enhance function and control. The AFO must effectively address both swing and stance phase deviations in order to

improve efficiency, decrease energy costs, decrease asymmetries and improve the overall quality of gait^{12,29,30}. Therefore, the ankle joint selection must provide an appropriate control of plantarflexion during swing and an appropriate control of plantarflexion and dorsiflexion during stance to minimize compensations and promote effective loading of the limb.

Direct control of the knee joint involves the use of orthotic designs that structurally bridge and mechanically control the anatomic knee joint as opposed to orthotic designs that mechanically influence the knee joint (i.e. AFOs). These types of designs would consist of a knee orthosis (KO) or knee-ankle-foot orthosis (KAFO). As previously stated, KOs are rarely indicated for the CVA population as they are unable to concurrently address the dysfunctions of the foot and ankle complex. Most sagittal plane knee deviations, specifically excessive flexion or excessive extension, present with loss of control of the foot and ankle and would ultimately be better addressed by an AFO or KAFO design.

Bellantoni et al suggested the use of KAFOs for stroke patients and reported a greater number of KAFO wearers developing the ability to walk 46 meters than the AFO wearers, specifically 55% vs. 25% respectively³¹. Kakurai and Akai reported clinical experience with a convertible KAFO to AFO used during gait training of CVA patients³². The primary purpose of the early fitting of the KAFO was to enhance initial stability and promote correct postural alignment, thereby encouraging weight transfer through the affected lower limb without fear of collapse. By preventing acquired disuse of the limb, many patients were downgraded to the AFO level at a later point in the rehabilitation process – specifically 64-77% of patients in an early treatment group vs. 22-40% of patients in a delayed treatment group.

Recently, mechanical knee joints have undergone significant design improvements by offering stance phase stability (locking) and swing phase mobility (free swing). This concept is similar to the "safety knees" used in lower functioning prosthetic patients. By providing a positive locking mechanism in stance and allowing the freedom to flex the knee in swing, improved gait efficiency and symmetry can be expected. Due to the recent introduction of these designs, little research is available relative to the use of these designs with the CVA population where KAFO prescription remains controversial.

EVALUATING STANCE PHASE DYSFUNCTION OF THE HIP

The hip joint functions as the dynamic link between the lower extremity and the trunk segment. By design, the ball and socket joint structure of the hip adapts to the demands or alignments of the distal foot, ankle and knee joints during loading. Loss of motor control, weakness and soft tissue contracture severely affect the hip joint's ability to provide stability to the trunk mass over the altered mechanical profile of the affected CVA limb.

Sagittal plane deviations of the hip during stance involve excessive flexion and inadequate extension, and are closely

associated with excessive knee flexion and extension. Excessive hip flexion at initial contact is most often the residual effect of an inadequate swing phase, with further hip flexion identified during the loading period. Stance phase stability is severely disrupted and associated deviations include increased ankle dorsiflexion, knee flexion, and increased lordosis with anterior pelvic tilt^{20,33,34}. Excessive hip extension during stance is rarely noted in the CVA population as they are more susceptible to hip flexion contracture which makes it impossible for the hip to ever reach full extension.

Excessive hip flexion is most likely to occur in the early stages of rehabilitation when flaccidity is present. Hip flexion contractures also maintain a flexed alignment of the hip and are often compensated for with increased lordosis and/or anterior trunk lean. Hip flexion contractures have been noted to develop secondary to immobility and lack of stretching rather than as a component of the neurological insult, and also that a majority of CVA patients evaluated had bilateral hip flexion contractures³⁵. With sustained hip flexion during stance, the thigh segment never reaches full extension in terminal stance in preparation for preswing. Without the powerful sagittal plane thrust of hip flexion, the patient is forced to develop a more horizontal strategy for limb advancement. This is usually evidenced by contralateral trunk lean and ipsilateral hip hiking in order to achieve swing phase of the affected limb.

EVALUATING SWING PHASE DYSFUNCTION OF THE HIP

Swing phase disruptions at the hip are potentially the most devastating to the development of an effective walking pattern. Loss of or ineffective hip flexion negates the advancement of the involved limb and can render the patient non-ambulatory. Many distal joint deviations, misalignments and motor dysfunctions can be addressed with an orthosis, but effective orthotic applications for hip weakness are not readily prescribed, utilized or indicated for CVA patients. At a minimum, fair hip flexor strength is required to advance the limb. Some patients are able to compensate for inadequate hip flexor function by externally rotating the limb and substituting hip adductors to create limb advancement.

With sufficient strength and control, exaggerated hip flexion during swing may be used to substitute for loss of control of the ankle. This allows the patient to obtain ground clearance for the plantarflexed foot during swing phase. Swing side circumduction and hip hiking may also accompany this compensation. If the exaggerated hip flexion is not limited by terminal swing, then the distal limb segment fails to experience momentum into full knee extension in preparation for loading. The resultant gait deviation includes shorted step length with a flexed limb during initial loading.

Extension of the hip during preswing and the large hip flexion moment during swing are critical in establishing the pendular motion of the limb during swing²⁶. Some patients compensate for the lack of swing phase activity by posterior pelvis tilt and posterior trunk lean at terminal swing. This posterior displacement attempts to advance

the swing limb, but also likely increases energy costs as 70% of the body mass (trunk, head and arms) is moving in a posterior direction while the patient is attempting to advance in an anterior direction.

ORTHOTIC MANAGEMENT OF THE HIP

Few, if any, orthotic applications extend to provide direct control of the hip joint. Generally, hip joint function, range of motion and alignment is addressed by physical therapists during rehabilitation and gait training programs. For the CVA population, the hip is especially susceptible to loss of motor control and muscle weakness, often resulting in contracture formation due to decreased activity levels and increased periods of sitting.

As mentioned, the hip joint responds to the demands imposed by distal joint alignments and therefore receives considerable indirect support through the use of an AFO or KAFO.

Nadeau et al³⁶ reported that CVA patients with both strong ankle plantarflexors and hip flexors were able to obtain the fastest walking speeds, and subjects having weak ankle plantarflexors and hip flexors were not able to produce an effective walking pattern. Subjects having either strong plantarflexors or strong hip flexors were able to compensate for weakness by overuse of the strong muscle group and were able to achieve ambulation abilities. However, weak plantarflexors were more easily compensated for than weak hip flexors, and hip flexor weakness is a very significant limitation to the ability to obtain walking skills.

OVERALL INFLUENCE AND EFFECT OF ORTHOTIC MANAGEMENT

Many studies have been performed to evaluate and validate the use of lower extremity orthoses for the CVA population^{4,5,8,16,17,29,33,37-40}. Positive outcomes of orthotic management have been proven to be: reduction in energy costs, improvement in the ability to perform activities of daily living and instrumental activities of daily living, increases in independent walking abilities, substitution for weak or dysfunctional muscles, prevention of joint deformity, reduction of pain, improvements in temporal gait variables, and improvements in weight distribution. The overall effect on the reduction of spastic or hyper-tonic limb conditions has not been clearly identified or defined as no clear consensus has been reached^{5,34}. Still, it has been suggested by others that AFOs may impose functional and/or mechanical restrictions on the walking pattern of CVA patients¹⁴, producing some of the abnormal or asymmetrical components commonly observed during observational gait assessment. The application of gait training was not reported in this study, which has been shown to have a significant effect on the outcome of the orthotic rehabilitation program.

The short-term efficacy of lower limb orthotic intervention for the CVA population is well documented in the literature, however, the long-term efficacy remains in question. It is known that the overall quality of the hemiplegic CVA

gait decreases over time. Specific factors are unclear and may relate to the progression of neurological consequences, reduction of activity level, ineffectiveness of orthotic designs relative to a changing patient profile, discontinuation of physical therapy treatment programs, or a combination of these and other factors.

The role of a lower limb orthosis may be to realign the anatomical structures, enhance function, decrease pain, prevent or correct deformity, immobilize joints, reduce axial load, improve static and dynamic postures, and/or improve balance capabilities^{5,21}. Ambulation aids such as orthoses have been shown to increase overall speed, stride length, cadence, reduce oxygen consumption, and reduce oxygen cost⁴¹. A majority of the literature relates the effect of AFOs on overall gait patterns. Greater focus is needed on the effect of orthotic intervention on the knee and especially on the hip of the CVA population.

IMPLICATIONS FOR FUTURE RESEARCH

There are many limitations in current orthotic designs available for use in the rehabilitation of CVA patients. First, basic orthotic design principles vary in the degree to which they address the complexities of the CVA patient. Existing triplanar deviations and deformities must be addressed at each joint and in each plane in which they occur to establish a mechanically effective alignment. Consideration of potential joint instabilities or deformations relates to the individual pathomechanical profile, compensatory walking pattern, and predisposition to joint laxities and contracture formation.

Second, by nature, many of the materials and components used in conventional orthotic designs offer limited adjustability in terms of rigidity vs. flexibility, limited vs. enhanced or controlled joint ranges of motion, deviations in alignment and discrepancies of function between anatomical and mechanical joint axes, and insufficient mechanical compromises between stability and mobility.

Third, rehabilitation program often focus on the initial and immediate needs of the CVA patient. After six to 12 weeks, depending upon the severity of the involvement, many CVA patients are left to re-establish and refine independent gait patterns without further training or supervision. This often allows the development of many functional yet inefficient compensations used to promote walking abilities. Continued gait training, muscle conditioning, stretch and balance program may greatly enhance long-term walking abilities and community ambulation skills.

A fourth point to consider is that significant emphasis is placed on disruptions in preswing leading to ineffective swing^{7,9,12,14,21,26,28,42}. Unfortunately, a majority of focus of lower limb orthotic design remains on the ability to limit plantarflexion throughout swing phase in preparation for an effective heel-toe contact. Midstance stability is effectively addressed by minimizing excessive knee and hip flexion and extension. The greatest failing in current orthotic designs is the lack of specification of terminal stance and preswing mechanical requirements and functions.

Finally, these patients must not be forgotten or excluded from follow-up based on the notion that recovery has stopped six months after the trauma. Small but significant gains can be made and will require individual attention, adaptation of therapy programs and adjustments to the orthotic prescription and/or design to maximize individual outcomes for each patient.

SUMMARY

Effective lower extremity orthotic management of the CVA patient is challenging throughout all stages of the rehabilitation process. Walking is the primary goal and is representative of both degree of recover and level of independence. Safe and effective walking promotes social acceptance and allows reintegration back into pre-existing lifestyles. Rehabilitation healthcare clinicians are tasked with providing qualitative and quantitative evaluation of each individual in order to develop effective treatment strategies to best enhance the recovery of motor skills and abilities. Effective orthotic designs are required to enhance and/or substitute for lost function and control without preventing or disrupting the natural recovery process. The short- and long-term needs of each patient must be predicted to better meet the needs of each patient as well as substantiate the allocation of limited financial resources.

Appendix A						
Aim 1 – Evaluation of Common CVA Gait Characteristics						
Author	Year	Study Type	Quality Rating	Population	Intervention	Outcomes Measured
Barela, Whittall, Black et al.	2000	Case control study	IV	18 non-disabled into 3 groups; matched to age and gender of 6 CVA patients	Imposed walking speed	Stride; affected vs. unaffected limbs; walking speeds; intralimb coordination
Bhakta	2000	Expert opinion	VII	CVA	Review of literature	Effect on spasticity
Blanton, Grissom, Riolo	2002	Case report	VI	44-year-old female, post-CVA	AFO, tibial nerve block, physical therapy	Dorsiflexion range of motion
Bohannon	2001	Expert opinion	VII	CVA	Review of literature	Ambulation independence, speed, distance, appearance, and energy expenditure
Kerrigan, Karvosky & Riley	2001	Case control study	IV	20 non-disabled matched to 20 patients with spastic paretic stiff-legged gait	None	Joint kinetic data
Kerrigan, Roth & Riley	1998	Cohort study	III	5 adult spastic paretic stiff-legged gait	3 patients had quadriceps block, 1 patient had hamstring block	Comparison of gait kinematics pre- and post blocks
Kim & Pohl	2000	Systematic review	I	CVA	None	Muscle weakness measured via Cybex II or hand-held dynamometers
Kramers De Quervain, Simon, Leurgans et al.	1996	Cross-sectional survey	V	18 CVA patients	Assessment occurred within 1 week of resuming independent walking	Gait analysis with motion analysis, forceplate recordings and dynamic surface electromyographic studies
Lee, Kerrigan & Della Croce	1997	Cross-sectional survey	V	41 patients with bilateral hip flexion contractures secondary to neurological insult	Thomas test, walking trials	Hip range of motion related to gait performance
Moore, Schurr, Wales et al.	1993	Expert opinion	VII	CVA	Literature review	Gait kinematics
Nadeau, Arsenault, Gravel et al.	1999	Cohort study	III	26 CVA with hyperextension matched with control group	Electrogoniometric feedback and/or physical therapy	Knee hyperextension
Riley & Kerrigan	1998	Cross-sectional survey	V	10 CVA with stiff-legged gait	None	Contribution of rectus femoris and hamstrings to stiff-legged gait
Yelnik, Albert, Bonan et al.	1999	Cross-sectional survey	V	135 CVA patients	Neurological examination	Overactivity of knee and ankle extensors
<p>Evidence Statement: A great deal of information is available describing gait deviations of the CVA population. Minimal information is available relative to the specific causes of each gait deviation and/or patterns of deviations. Most of the information is gathered from cross-sectional surveys.</p> <p>Grade of Recommendation: C</p>						

Appendix B						
Aim 2 – Effectiveness of Orthotic Treatment Programs on the Hip and Knee						
Author	Year	Study Type	Quality Rating	Population	Intervention	Outcomes Measured
Beckerman, Becher, Lankhorst et al.	1996	Randomized controlled trial	IIa	60 CVA patients	Thermocoagulation of the tibial nerve and an AFO	Change in spasticity, muscle tone, ankle clonus, Achilles tendon reflex, ankle range of motion, motor function of the leg and balance
Beckerman, Becher, Lankhorst et al.	1996	Randomized controlled trial	IIa	60 CVA patients	Thermocoagulation of the tibial nerve and an AFO	Changes in walking ability and walking speed
Chen, Yeung, Wang et al.	1999	Cross-sectional survey	V	Convenience sample of 24 subjects	Anterior AFO	Postural sway, postural symmetry, and dynamic postural stability
Chu & Reddy	1995	Expert opinion	VII	N/A	AFO	Stresses incurred by the AFO during normal walking
Dieli, Ayyappa & Hornbeak	1997	Case reports	VI	3 CVA patients	Dynamic AFO	Comparison of stride characteristics
Dittmer, MacArthur-Turner & Jones	1993	Systematic review	I	CVA	Literature review	Temporal and kinematic aspects of gait
Esquenazi & Hirai	1991	Systematic review	I	CVA or brain injury	Literature review	Kinetics and kinematic aspects of gait
Franceschini, Massucci, Ferrari et al.	1989	Case report	VI	13 CVA patients	AFO	Perry and Garret Walking ability questionnaire scale
Gok, Kucukdeveci., Altinkaynak et al.	2002	Cross-sectional survey	V	12 CVA patients	AFO	Spatiotemporal, kinematic and kinetic parameters
Hesse, Gahein-Sama & Mauritz	1996	Cross-sectional survey	V	194 CVA patients who received at least one technical aid	Questionnaire	Level of satisfaction, frequency of use, punctuality of delivery and cost coverage
Hesse, Luecke, Jahnki et al.	1996	Cross-sectional survey	V	19 CVA patients	Firm shoes and AFO	Cycle times, vertical ground reaction forces, trajectories of the center of pressure
Hesse, Werner, Matthias et al.	1999	Cross-sectional survey	V	21 CVA patients with equinovarus deformity	AFO	Limb-dependent cycle parameters, gait symmetry, vertical ground reaction forces, sagittal ankle excursions and kinesiological electromyogram of several lower limb muscles
Hoening, Horner, Duncan et al.	1999	Expert opinion	VII	CVA	Literature review	Benefits of rehabilitation services
Isakov, Mirshi, Onna et al.	1992	Case report	VI	3 patients with genu recurvatum	KO and AFO	Stance time difference, stride distance and velocity
Kakurai & Akai	1996	Case report	VI	28 CVA patients	Convertible KAFO	Ambulation capabilities
Lehmann, de Lateur & Price	1992	Expert opinion	VII	CVA	AFOs and KAFOs	Gait assessment and oxygen consumption
Miyazaki, Yamamoto, Ebina et al.	1993	Expert opinion	VII	8 healthy subjects	AFO	Effect of dorsi/plantarflexion flexibility on gait
Miyazaki, Yamamoto & Kubota	1997	Cohort study	III	20 CVA patients	AFO	Effect of dorsi/plantarflexion flexibility on gait; and initial angle
Mueller, Cornwall, McPoil et al.	1994	Case report	VI	55-year-old CVA	Dynamic AFO	Foot-loading data
Nagaya	1997	Expert opinion	VII	N/A	None	Dorsiflexion and plantarflexion angles of AFOs vs. applied force
Romero & Rice	1992	Case report	VI	6.5-year-old subject with genu recurvatum	KAFO	Independent ambulation, qualitative assessment
Teasell, McRae, Foley et al.	2001	Cohort study	III	423 CVA patients	Discharge with AFO	Functional outcome via Chedoke-McMaster Stroke Impairment Inventory, FIM and Berg Balance Scale scores
Tyson, Thornton & Downes	1998	Case report	VI	4 CVA patients	Hinged AFO	Velocity, stride, step length and symmetry
Tyson & Thornton	2001	Cross-sectional survey	V	25 CVA patients	Hinged AFO	Stride length, step length, symmetry, cadence and velocity
Weiss, Mulroy, Gronley et al.	2002	Case report	VI	10 CVA patients	Three types of AFOs	Velocity, stride length, cadence, and joint kinematics
Wong, Tang, Wu et al.	1992	Cross-sectional survey	V	68 CVA patients	Anterior AFO	Step length, step width, stance phase %, single and double support %
Yamamoto, Ebina, Miyazaki et al.	1997	Cross-sectional survey	V	33 CVA patients	Various AFO designs	Magnitude of dorsiflexion assist moment and initial ankle joint angle
Yamamoto, Ebina, Kubo et al.	1999	Cross-sectional survey	V	5 CVA patients	Various AFO designs	Magnitude of dorsiflexion assist moment and initial ankle joint angle
Yamamoto, Miyazaki & Kubota	1993	Cross-sectional survey	V	15 CVA patients	Experimental AFO	Significance of corrective moments of AFOs

Evidence Statement: The literature suggests that orthotic intervention has the ability to effect gait kinematics and kinetics in the CVA population. A majority of CVA patients receiving orthotic management are fit with a prefabricated or custom AFO. Further research is needed to determine specific design features relative to changes in gait kinematics and kinetics.

Grade of Recommendation: C

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PHYSIOTHERAPY MANAGEMENT OF UPPER EXTREMITY COMPLICATIONS AFTER STROKE: HEMIPLEGIC SHOULDER PAIN, SPASTICITY AND RELATED SYNDROMES - A LITERATURE REVIEW (R9-A)

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INTRODUCTION

Stroke is the third highest cause of death in the UK, is the most significant cause of disability, and requires 4% of National Health Service expenditure to treat¹. It is a National goal in the UK, for health care practitioners and politicians, to manage this complex condition more effectively and to apply evidence-based clinical practice where possible. As a result, documents published by the Royal College of Physicians (2000)² and the Scottish Intercollegiate Guidelines Network – SIGN (2002)³ provide evidence-based, graded recommendations for interventions in stroke rehabilitation. Some of these have a direct bearing on this subject area. Physiotherapy for stroke is broadly divided into therapeutic strategies aimed at recovering movement and function lost as a result of the brain lesion, and the prevention and management of secondary complicating features such as pain and stiffness in the musculoskeletal system^{2,3}. Clearly, stroke patients do commonly develop orthopaedic⁴ and long-term pain syndromes^{5,6}. The emphasis of this paper is upon defining the evidence-base for physiotherapy interventions in post-stroke physical impairment of the upper extremity resulting from secondary complications. Modalities such as Functional Electrical Stimulation (FES/ES), Transcutaneous Electrical Nerve Stimulation (TENS/TNS) and orthotic interventions, although associated with physiotherapy intervention, will be addressed elsewhere in the document.

The literature related to upper limb complications after stroke is predominantly concerned with hemiplegic shoulder pain (HSP), shoulder subluxation, reflex sympathetic dystrophy (RSD), spasticity, contracture and various other less common syndromes. Publications addressing these issues are extensive, hugely varied, and diverse. They tend to be characterised by literature reviews (some systematic), attempts to understand patho-physiology through anatomical/biomechanical essays, establishment of measurement tools and intervention studies utilising a variety of methodologies. HSP, which accounts for the bulk of the literature, may be a large problem within some patient groups after stroke, with a range of frequencies scattered between 5% and 84% reported by different authors^{7,8,21}.

SEARCH STRATEGY

This strategy comprised searches of various databases including RECAL, Pubmed, Medline, Cinahl, M-Base, Web of Science, and the Cochrane Collaboration Systematic Reviews and Trials databases from 1983-2003. Terms comprising stroke and shoulder, upper limb, hands, pain, spasticity and contracture singly and in all permutations were used to search until August 2003. Literature addressing post-stroke pain of central origin was not included unless shoulder, arm or hand pain was a core consideration. Literature reviews, epidemiological studies and other non-

intervention studies are presented as a sequential narrative. There are so many such papers that an individual appraisal and quality rating of each would be impossible. However, all are mentioned in the text and recent review articles of high quality exist to expand the reading if desired. This paper focuses on intervention studies in more detail in order to establish the evidence base for physiotherapy practice in stroke upper extremity complications. See Appendices A-F for summaries.

ANATOMICAL CONSIDERATIONS

Various authors provide essays which attempt to relate the anatomical and biomechanical aspects of the shoulder joint complex with a view to developing an understanding of the pathophysiological nature of HSP and other upper limb copathologies^{4,7,9,10,29}.

The glenohumeral joint is associated with the scapulothoracic, acromioclavicular and sternoclavicular joints in forming a complex which is intrinsically unstable. It is designed for maximum mobility to allow the hand to be placed anywhere within a large space around the body. Complete range of motion also depends upon sufficient spinal and thoracic flexibility to allow the appropriate positioning of the shoulder girdle. This establishes the dynamic alignment of the glenoid cavity required to achieve appropriate scapulohumeral rhythm, normal movement of the upper limb and the ability to place the hand in space. The tonic activity of the surrounding musculature is central to maintaining a degree of stability to prevent frequent dislocation.

Stability is provided by the action of supraspinatus and deltoid muscles (posterior fibres), the coracohumeral ligament, the glenohumeral joint capsule and the upward angulation of the articular surface of the glenoid cavity, in relation to the humeral head.

The stroke which renders the patient hemiplegic will, to a varying degree, interfere with this mechanism and as a result the potential to develop HSP and other upper limb complications is created through the effect of gravity. This will be more or less apparent depending on the amount of support available and the position occupied by the patient. Initial hypotonus in the supporting musculature may cause a downward rotation of the glenoid cavity in association with a lack of approximation of the humeral head within the glenoidal labrum leading to the likelihood of joint malalignment and resultant soft tissue trauma through stretching and ischaemia. The loss of truncal control and associated flexed posture commonly seen after stroke will contribute to this situation by influencing the angle of the scapulothoracic junction, thereby further affecting glenohumeral alignment.

Should spasticity be generated around the shoulder complex, most commonly seen in the large internal rotators such as pectoralis major, latissimus dorsi and teres major¹¹

then the malalignment may cause impingement of the bony surfaces through over-approximation of the glenohumeral joint. Subsequent attempts to move the arm through active or passive range may result in damage to pain-sensitive structures and the onset of HSP¹². Dynamic proximal stability of the scapula in relation to the humerus during large range flexion and abduction movements (scapulo-humeral rhythm) is important in maintaining the appropriate anatomical relationship between the glenoid cavity and the humeral head¹⁰.

This concept has generated attempts to quantify scapular mobility and alignment throughout the range of upper limb movement. The absolute relationship between scapular alignment and subluxation or shoulder pain after stroke remains unclear with some evidence to support downward rotation of the glenoid in both shoulders after stroke^{13,14,15}.

HEMIPLEGIC SHOULDER PAIN

Various theories have been suggested to explain the onset of HSP^{16,17,18}, although there have been no studies to absolutely verify these and there has been considerable disagreement between different authors. Suggested causes include improper handling and positioning¹⁹, abnormal muscle tone (increased or decreased)^{8,18,20}, subluxation²¹, capsular contracture²² (seen in 77% patients with HSP), shoulder-hand syndrome^{23,24}, thalamus syndrome^{25,26} (resulting in centrally perceived post-stroke pain), brachial plexus lesions²⁶ and pre-existing local orthopaedic conditions such as osteoarthritis, adhesive capsulitis and rotator cuff tears⁴. There is some evidence to suggest that HSP is linked to Central Post Stroke Pain syndrome (CPSP). A sample of 182 stroke patients was prospectively tested for sensory disturbance; specifically of thermal perception. Those who had impaired sensation were more likely to develop HSP²⁵. However, there does not seem to be a relationship with hemineglect²⁷. The broadest estimate of the size of the problem ranges from 5% to 84%²¹ (Table 1 - Appendix A). In a very recent prospective study of a large cohort of 1761 stroke patients²⁸, self-reported shoulder pain among survivors increased from 256/1474 (17%) at one week, to 261/1336 (20%) at one month and 284/1203 (23%) at six months. The risk of shoulder pain was highest in those with the most severe motor deficit as seen in an inability to shrug the affected shoulder²⁰.

An examination of the statistical relationships between shoulder pain in hemiplegia and five variables, revealed that loss of range of shoulder external rotation was the most significant factor³⁰. Case-mix may also be a factor which appears to be under-reported. Authors have not made it clear whether they are reporting HSP incidence, prospectively and longitudinally, or prevalence cross-sectionally at any one time within a population, or simply the frequency with which they have identified the problem in a sample and so comparability is difficult between studies.

In an attempt to identify the source of pain a series of single-case studies on a group of 97 patients at least 3 months post stroke with HSP was performed³¹. Patients received an injection of 10 mls 1% lidocaine into the structure

felt to be the source of their pain (followed by a second, into the area of the remaining pain if no initial relief was achieved). Findings suggested that 43% had subacromial bursitis (especially those with "mild" hemiparesis), 33% had capsulitis (predominantly those with more severe hemiparesis), 24% were classified as "other." Thirty-three percent of the patients had radiating pain into the arm. It was also found that movement aggravated the symptoms in 64% of cases and that a significant relationship existed between HSP and loss of range of motion.

Stroke patients in general appear to have significantly more problems initiating sleep than controls and those stroke patients with HSP had significantly more sleep disturbances³². These patients also scored more highly on the Hospital Anxiety & Depression Scale than did the controls. It is not absolutely clear from this study that depressive illness was not the significant factor in the sleep disorder rather than the HSP. These authors postulate that it is the cumulative effects of pain, anxiety and depression which may contribute to the disturbances in sleep for patients following stroke. The range of estimates of the frequency of HSP may not reflect a true variation of the manifestations of this stroke complication²⁸. This may be explained by:

1. Lack of consensus on definition
2. Lack of agreed diagnostic criteria
3. Low inter-rater reliability of diagnostic assessment
4. Differences in type and severity of stroke
5. Timing of assessment and length of follow-up
6. Different management regimes, some of which may alter frequency
7. Random variation

MEASUREMENT – QUANTIFYING HSP

The measurement of pain is difficult at best, given that its perception and reporting by humans is so individual and subjective and may be related to behaviours within different cultures^{33,34}. However, in a population of stroke patients with symptoms which may include communication deficits as well as cognitive, visuospatial and dysaesthetic abnormalities the accurate study of this problem is further complicated. Indeed, many authors exclude patients with dysphasia from their analyses and the resultant selective sampling questions the validity and subsequent ability to generalise their results to the larger stroke population. Most forms of visual analogue scale (VAS), the common means of assessing pain, require sufficiently high levels of communicative ability as to exclude many of the stroke population who are aphasic. Even stroke patients who are not aphasic have great difficulty quantifying their perceptions of standard sensory experiences using common visual/verbal scales such as mechanical, vertical and horizontal visual analogue scales (VAS), 4-point rating scales and numerical rating scales³⁵. Visual analogue scales generated the poorest performance with only 47% of a population of strokes (with severely aphasic patients excluded) able to use them correctly. When stroke subclassification³⁶ is taken into account, the most severe category, Total Anterior Circulation Syndrome strokes, were only 16-28% successful

in using any type of VAS, presumably through the implicit visuospatial and cognitive impairments. These, also being the most physically impaired, may be the most susceptible individuals to develop HSP, and this case-mix issue may explain in part the large variation in the reported size of the problem^{29,31}.

A well-known scale for measuring joint pain in rheumatoid arthritis³⁷ called the Ritchie Articular Index (RAI) has been specifically modified and tested for use with HSP³⁸. These authors found high (Kappa 0.76) inter-rater agreement in the diagnosis of shoulder pain in a group of 34 patients with stroke. HSP has also been quantified using a comparison of the RAI and the SROMP (shoulder lateral rotation range of motion measured at the point of pain). The SROMP involves the passive external rotation of the affected humerus until a pain response is elicited.

The pain-free range is then measured in degrees using a liquid goniometer attached to the wrist and pain is then expressed as a numeric value according to the range of motion. This test also achieved high inter-rater reliability (intraclass correlation coefficients of 0.874 - 0.989 between two raters) and correlated with the RAI³⁹.

The Physiotherapy Assessment Tool (PAT)⁴⁰ was developed by gathering expert advice using direct observation of clinical practice, interviews and focus groups. This tool is designed to facilitate clinical reasoning and aid management of the patient. The PAT was evaluated for inter- and intra-observer reliability using a sample of 26 stroke patients and two raters⁴¹. Agreement for items, scored using the kappa co-efficient, ranged from moderate to very good reliability across the scale.

The difficulty with VAS has prompted the development of a scale of pain intensity for post-stroke shoulder pain⁴². This is known as the SPIN and constitutes a 6-point ordinal scale which is coloured red for visual impact. Validity and reliability were established with 72 individuals from rheumatology and chronic pain clinics. The SPIN was found to be easy to use and correlated well with VAS and a 10-point numerical rating scale. Work is in progress to test this measure in a sample of stroke patients.

Physiotherapists' ability to measure post-stroke shoulder pain using Visual Analogue Scales for intensity, frequency and affective response, and a "categorical site of pain" scale has been the subject of investigation⁴³. Three physiotherapists rated 33 stroke patients. Results suggest acceptable inter-rater reliability for intensity and frequency, but there was a large systematic bias between pairs of raters.

MRI (MAGNETIC RESONANCE IMAGING)

Imaging techniques have become sufficiently sophisticated to allow the detailed examination of musculo-skeletal structures *in vivo*, having been in routine use for the assessment of shoulder disorders since 1986⁴⁴. Although no specific articles have been published to address the problem of HSP with MRI, several authors have considered the shoulder as a subject for detailed investigation. This has developed within the context of achieving an understanding of the magnetic resonance infrastructural details of the normal shoulder joint⁴⁵. The excellent soft tissue contrast, high

spatial resolution, multiplanar capability, and non-invasive nature of MRI lend it to this particular investigation^{46,47}. In specialist units, high diagnostic accuracy can be achieved for full thickness rotator cuff tears, although there are still difficulties for partial tears and tendonitis⁴⁸. It is suggested that two-echo spin-echo imaging with proton-density and T2-weighted technique in three planes provides the most information⁴⁹. The appropriate planes to view maximally the relevant anatomical structures are oblique coronal, oblique sagittal and axial planes with 3mm slice thicknesses and a 1mm gap.

In a series of single case studies of patients with post-stroke HSP (unpublished data, 2000) who underwent MRI of both shoulders, there were found to be significant differences between the images of each shoulder. The anomalies included partial and complete rupture of the rotator cuff, calcification of supraspinatus tendon, thickening of the joint capsule, subacromial bursitis and osteophytic changes around the bony margins of the glenohumeral joint. A specialist orthopaedic radiologist, who was blind to the clinical presentations of the subjects, reviewed the images and demonstrated high agreement with the pathological changes seen in the images. However, he also admitted to having seen similar changes on images of other patients without shoulder pain, so that differences in the images between the two shoulders may not have been correlated with the HSP. However, this may yet be a potentially successful means of improving diagnosis in the hemiplegic shoulder and warrants further study.

PHYSIOTHERAPY IN THE TREATMENT OF HEMIPLEGIC SHOULDER PAIN

Attempts to locate papers of good methodological quality proved difficult. Of eight RCTs of physiotherapy for stroke in the Cochrane Library Trials Database (2003)⁵⁰, none reported interventions in any aspect of upper limb impairment other than that associated with the focal neurological impairment. In a search of 4 Cochrane Reviews and one protocol, none specifically addresses physiotherapy for HSP. None of the studies which currently exists describing physiotherapy intervention for HSP is included in the Cochrane Review of physiotherapy for shoulder pain⁵¹. Those reviewers found 26 randomised controlled trials which did meet the Cochrane inclusion criteria. Of these, there is some weak evidence to indicate that the following physiotherapy interventions may be of benefit in the treatment of shoulder disorders in general:

- Exercise for rotator cuff disease augmented by mobilisation of the shoulder – 2 trials^{52,53}
- Laser therapy for adhesive capsulitis - 3 trials^{54,55,56}
- Pulsed electromagnetic field for rotator cuff disease – 1 trial⁵⁷
- Ultrasound and pulsed electromagnetic field for calcific tendonitis - 2 trials^{58,59}
- Ultrasound does not appear to afford any benefit over exercise alone – 1 trial⁶⁰

- Corticosteroid injection more effective than physiotherapy interventions for rotator cuff disease - 5 trials^{61,62,63,64,65}
- No evidence to support physiotherapy alone in the treatment of adhesive capsulitis of the shoulder - 1 trial⁶⁶
- Supervised exercise regime is of benefit in the short and long term for mixed shoulder disorders and rotator cuff disease - 4 trials^{67,68,69,70}

None of these interventions have been trialled in the management of HSP and in those interventions for HSP which have been reported, the methodological quality was not sufficient to meet inclusion criteria. The same authors had published a systematic review of physiotherapy interventions for the shoulder in 1998 and again no trials of stroke physiotherapy could be included⁷¹. The Cochrane collaboration recommends that there is a clear need for trials of physiotherapy interventions in shoulder pain in general, and the hemiplegic shoulder in particular.

A recent, well-conducted systematic review⁷² reported the methodological quality of intervention studies for hemiplegic shoulder pain. There were no exclusions with respect to study design. These authors challenged the assumption that the RCT is always superior to other designs such as cohort studies, as has often been the case in systematic reviews and evidence-based guidelines³. Applying their criteria list for methodological scoring, the three highest rated studies^{73,74,75}, and therefore those potentially contributing most to the evidence base, were not RCTs. The results of this review suggest that the most promising interventions for HSP, although requiring more detailed investigation, are FES and intra-articular triamcinolone acetonide injections.

Recent work has focused on the identification of the key factors associated with the complex package of care received by stroke patients⁷⁶. These authors aimed to describe the current interventions used by therapists and nurses in the management of HSP. Six nurses, five occupational therapists (OTs) and six physiotherapists (PTs) were interviewed; 12 nurses, 12 OTs and 12 PTs were sent a pilot questionnaire; and finally, 332 nurses, 332 OTs and 332 PTs were sent the main questionnaire. One hundred and seventy-five different types of intervention were described (response rate 57.8%) providing an incredibly detailed profile of interventions which may support further research. In recent surveys of current practice in physiotherapy for HSP, the emphasis was on the institution of "correct" techniques for moving, handling and positioning⁷⁷ considered fundamental to neurological physiotherapy^{78,79}.

A national survey to determine current approaches to the treatment of hemiplegic shoulder pain in the Netherlands⁸⁰ was applied to 100 PTs, 100 OTs, 100 rehabilitation physicians and 100 neurologists, all actively involved in the treatment of stroke patients. Fifty four treatment combinations were reported. The first choice of treatment for HSP was physiotherapy (32%), prevention/instruction/education (22%), oral medication (8%), local injection (7%), sling (4%), referral (3%), other therapies (4%) and combinations (20%).

Two recent publications have reviewed the evidence base to inform²¹ and develop⁸¹ an integrated care pathway (ICP) for the management of HSP after stroke. These authors found that HSP occurs in two distinct "flaccid" and "spastic" presentations and suggest clinically-reasoned management strategies based on this. An ICP was then developed by a multidisciplinary team combining, clinical consensus with a systematic literature review. The benefits of this appear to be increased awareness of HSP by staff and further study may establish whether there is a beneficial effect on the frequency and severity of HSP.

There have been some recently published studies evaluating specific physiotherapy interventions for HSP. These are shown in Table 2 (Appendix B). Subjects for investigation have included handling techniques⁸², physical rehabilitation⁸³⁻⁸⁶, Transcutaneous Electrical Nerve Stimulation (TENS)^{87,88,89}, Cryotherapy⁹⁰, EMG biofeedback⁷⁵ and ultrasound⁹¹.

As HSP is such a complex syndrome and stroke patients require such a multifaceted management strategy by many disciplines, it would seem logical, on the basis of the evidence, to approach the prevention and treatment of this distressing condition in a prospective and comprehensive fashion. Specific therapies can be applied in specific cases within this structure on an individual basis.

SPASTICITY

Spasticity is a well-recognised complication of stroke⁹². It is commonly defined as:

"velocity-dependent hyper-excitability of muscles to stretch, characterised by exaggerated tendon reflexes, increased resistance to passive movement and hypertonia, resulting from loss of upper motor neuron inhibitory control" - Lance 1976⁹³ "The Wartenberg Lecture"

The reliability of measurements regarding presence and degree of spasticity after stroke has been investigated⁹⁴⁻⁹⁷. The Ashworth Scale⁹⁴ and the Modified Ashworth Scale^{95,96,97} have been demonstrated as having moderate to high levels of reliability for a single tester, but reliability between raters was not good⁹⁷. Spasticity was deemed to be present in 38% of a sample of 106 stroke patients assessed at a number of joints using the Modified Ashworth Scale and the Tone Assessment Scale⁹². In another study, 70% of 189 stroke patients assessed with the Modified Ashworth Scale were found to have spasticity⁹⁸. It is interesting to note that of this sample, 98 (52%) had haemorrhagic strokes. This may be a factor in the high frequency of spasticity within this sample. Various other methods have been investigated in the quantification of spasticity, including static dynamometers^{99,11} and quadratic weights¹⁰⁰.

There is evidence to suggest that spasticity is associated with HSP^{7,8,27,31} and that spasticity presents an inverse relationship with motor recovery of the upper limb¹⁰¹. This may be related to the tendency for common presentations of infarction in middle cerebral artery territory (perfusing motor and sensory cortices representing upper limb predominantly) to render patients hemiplegic with a bias toward arm weakness¹⁰².

PHYSIOTHERAPY IN THE TREATMENT OF SPASTICITY

Current physiotherapy practice in the UK tends to follow the modern form of the Bobath concept for the treatment of neurological patients^{43,76,78,79,103}, with some 67% of respondents in a National survey of PTs in the UK claiming that it was their preferred approach. However, science has thus far failed to demonstrate the superiority of this approach over others¹⁰⁴. Associated reactions (ARs) are limb movements that may be observed in stroke patients either following effortful movements or during activities such as sneezing, coughing and yawning¹⁰⁵. They are considered to hinder the development of normal movement and as such are a focus for physical management of patients by physiotherapists¹⁰³. However, it has also been suggested that ARs do not contribute to the development of an established spastic state or the contracture of soft tissues^{105,106}. Physiotherapy and conventional orthoses are central to the management of spasticity, but other promising interventions include phenol chemo-denervation, electrical stimulation, botulinum toxin and oral tone modifying drugs¹⁰⁷. Several studies have evaluated specific physiotherapy approaches to the treatment of spasticity (Table 3 – Appendix C). However, methodological issues make the extrapolation of these data to the clinical environment difficult. Trials of TENS⁸⁸ and EMG biofeedback¹¹³ have produced encouraging results.

SUBLUXATION –INTERVENTIONS STRAPPING AND SUPPORTS

Whether or not glenohumeral joint subluxation is a significant factor in the development of HSP remains a matter for debate²¹. Some authors have reported a causative relationship^{7,8,115,116} whereas others have not^{20,26,31,39,117,118}. As a result of perceived biomechanical anomalies generated around the shoulder after stroke it has become an integral part of physiotherapy practice to address this issue prospectively^{77,78,79,80}. In a study to compare the validity of three types of clinical measure of subluxation against radiographic imaging of the shoulder, a group of 20 stroke patients were assessed according to palpation of the shoulder joint, arm length discrepancy and thermoplastic jig. These were assessed with regard to their accuracies in identifying subluxation in patients who had the extent of glenohumeral malalignment confirmed by X-ray¹¹⁹.

The most effective method of detection proved to be palpation, although the authors felt that the other methods may have a role to play in the grading of the degree of subluxation during therapeutic techniques to realign the upper limb during positioning strategies. A three point scale of subluxation by thumb palpation (scored as none [0], minimal [1], or substantial [2]) has been reported, which showed 91.7% agreement between two raters assessing 28 patients³⁹. HSP measured using the RAI and the SROMP (shoulder lateral rotation range of motion measured at the point of pain) did not correlate with the subluxation scores. The use of supports for the hemiplegic shoulder has been identified as the subject of a proposal for a Cochrane Library Review which is not yet complete¹²⁰. Means of generating support of the apparently unstable joint have thus evolved and are

presented in Table 4 (Appendix D).

The Harris hemisling, the Bobath sling and arm trough or lap board have been compared in their relative abilities to re-align subluxation¹²². These authors studied 10 patients (8 stroke, 2 intracerebral space occupying lesion) with hemiplegia and X-rayed the affected shoulder of each patient wearing each device and compared this with radiographs of their unaffected shoulders. The Harris hemisling and arm trough achieved re-alignment similar to the uninvolved shoulder. The Bobath sling distracted the glenohumeral joint horizontally and was more variable. These authors recommend the use of the first two methods for the support of hemiplegic upper limbs. In a similar study, the effects of four different supports in the management of shoulder subluxation were evaluated¹²³. The single-strap hemisling, the Bobath roll, the Roylan humeral cuff sling and the Cavalier support were assessed as to their capacities to reduce the malalignment of the glenohumeral joints of 20 consecutive stroke patients by using antero-postero radiographic analysis. These authors found that the Bobath cuff (which differs from the Bobath sling mentioned above) and the Cavalier support both produced unwanted lateral displacements of the humeral head. The single-strap hemisling reduced the vertical displacement across the entire group, but the Roylan humeral cuff sling achieved the most effective reduction in total subluxation asymmetry measured by combining vertical and horizontal displacements on X-ray. In a biomechanical analysis of four supports¹²⁴, which were essentially identical to those above, it was found that slings with straps over the affected shoulder provide continuous support in the low-toned upper limb. Again, the Bobath roll produced lateral displacement and it was observed that lapboards must be maintained at an appropriate distance from the hemiplegic shoulder to be effective. In two surveys of Canadian therapists¹²⁵, carried out 10 years apart to determine their preferences for shoulder supports, it was apparent that the use of the Bobath Axial Roll had diminished. Lap boards, Single Sling and Arm Cuff Supports seemed to be most widely used.

Strapping of the hemiplegic shoulder has been the subject of two RCTs^{126,127} (Table 5 – Appendix E) and seems have some value as a short term measure in severe HSP and subluxation. In a comparative study of strapping versus sling support in 15 stroke patients with shoulder subluxation, strapping was found to achieve better alignment using X-ray than sling support¹²⁸.

*Clinical experience suggests that subluxation is a dynamic state which is dependent upon the relationship of the hemiplegic upper limb to gravity and the alignment afforded by a base of support or device. The author has seen many patients who report HSP either themselves, or through some other practitioner, who have full, pain-free range of motion and can be rendered pain-free through attention to appropriate handling and positioning strategies. At times HSP seems to come and go and is not necessarily a static phenomenon. Patients may present with high muscle tone and restricted shoulder ROM only to emerge after treatment with a low-tone subluxation!

REFLEX SYMPATHETIC DYSTROPHY, SHOULDER-HAND SYNDROME, COLD HEMIPLEGIC ARM

There is a general lack of differentiation between these terms in the literature and they may be synonymous and used interchangeably. A large prospective observation of a cohort of 829 surgical patients was performed in order to better understand the nature of this problem¹³⁰. Reflex sympathetic dystrophy (RSD) is thought to be caused by an abnormal sympathetic nervous reflex. It has been known by many names including Sudeck's atrophy, algodystrophy, causalgia and peripheral trophoneurosis and most recently, Complex Regional Pain Syndrome (CRPS) Type 1¹³¹.

Presenting signs and symptoms may include¹³⁰:

1. 4 or 5 from:
 - Unexplained diffuse pain
 - Difference in skin colour relative to other limb
 - Diffuse oedema
 - Difference in skin temperature relative to other limb
 - Limited active range of motion.
2. Occurrence or increase of above signs and symptoms after use
3. The above signs and symptoms present in an area larger than the area of primary injury or operation and including the area distal to the primary injury.

The presenting features of RSD appear to have an early and a late phase. The features of the early phase are characterised by the signs of acute inflammation (heat, swelling, redness and pain) in 93% of cases. The later stage involves tissue atrophy, involuntary movements, tremor, muscle spasms and pseudo-paralysis.

A longitudinal, prospective, observational analysis of 41 stroke patients undergoing in-patient rehabilitation revealed that 41% of these patients had evidence of pain, oedema and vasomotor changes in the affected upper extremity²³. A three stage progressive course of "Shoulder-hand Pain Syndrome" (SHS) was provided:

Stage 1	Stage 2	Stage 3
Pain plus: Oedema Vasomotor changes/ hyperhidrosis	Previous plus: Trophic skin/ nail changes Muscle atrophy Osteoporosis	Resolution of pain: Resolution of oedema Atrophy/ contractures Advanced osteoporosis

The frequency of SHS in patients with hemiplegia without proprioceptive deficit or visual neglect was 7%, whereas it was present in 61% of patients with a combination of hemiplegia plus impaired proprioception and visual neglect. However, a recent prospective study of 71 hemiplegic stroke patients¹³² identified 34.8% as having symptoms of CRPS Type 1 and identified motor deficit, spasticity, sensory deficits, and initial coma as prognostic factors. These authors found no relationship with shoulder subluxation,

unilateral neglect and depression with CRPS Type 1. Other authors have presented findings which suggest that shoulder subluxation is a causative factor in RSD¹³³.

Thirty-six patients who developed SHS from a selected middle cerebral artery territory stroke population of 132 were studied²⁴. Thirty-three of these patients developed supra-humeral pain one to four weeks before the onset of SHS. The patients were then included in a placebo-controlled, non-blinded trial, being allocated to either a corticoid (treatment) or placebo group. The treatment group was given 32mg. oral methylprednisolone daily for 14 days, then tapered over a further 14 day period. The placebo group was given placebo medication for 14 days and if no improvement in SHS symptoms was seen then they commenced the same methylprednisolone regimen as the treatment group. Thirty-one of the 36 patients treated with the corticosteroid (and standard physical therapy regimen) became and remained symptom-free, provoking the hypothesis that SHS is a predominantly inflammatory process.

A survey conducted in the UK sent 100 questionnaires to patients who had survived one year or more following stroke to establish the frequency of cold hemiplegic arm and any subsequent relationship with RSD¹³⁴. Forty-eight (64%) of the respondents experienced unilateral coldness in the hemiplegic upper limb, at a median time of one month post-stroke. Fifteen fulfilled the diagnostic criteria for RSD and thirteen of these had coldness of the arm. These authors proposed that patients who experienced cold hemiplegic arm were more likely to develop RSD.

Interventions for these syndromes have been the subject of a systematic review of the literature¹³⁵. Two studies were aimed at physical interventions in the management of this condition, but it has not been possible to source these papers, although the references are included^{136,137}. It was suggested that Continuous Passive Motion (CPM) combined with limb elevation results in greater reduction in finger stiffness and hand oedema than limb elevation alone¹³⁶.

Three papers^{138,139,140} were found which tested physical interventions for the possible symptoms of inflammatory soft tissue disorders of the upper limb after stroke. These are presented in Table 6 (Appendix F). It is likely that intermittent compression of the oedematous upper limb has no benefit over conventional physiotherapy in reducing swelling¹³⁹.

SUMMARY

Upper extremity complications constitute a large problem which may contribute to poor upper limb recovery, depression, sleeplessness and may be associated with poor overall functional outcome in patients following stroke. Physiotherapy is an intervention which is applied in many of these conditions. The difficulty in interpreting the literature relates to the fact that shoulder pain, for example, may be just one of many factors which has an adverse effect on upper limb outcome in patients with severe stroke^{141,142,143}. The standardised protocols used to define HSP and CRPS/SHS are very variable in their precision, making the interpretation of aetiology and frequency as well as the effects

of therapeutic interventions uncertain. Papers tend to be methodologically weak and make assumptions which raise questions about bias, making confident understanding of the problems, and subsequent interventions difficult. There continues to be a steady stream of review articles appearing in the literature regarding HSP, but a distinct lack of new intervention studies of sufficient methodological stature to contribute further to those reviews.

However, the evidence to support a comprehensive, cohesive, multidisciplinary management programme for the patient in general, and the upper limb in particular, is convincing from rehabilitation and research perspectives. The failure to staff adequately rehabilitation units with realistic numbers and skill-mixes to facilitate desirable levels of patient care remains an issue in the NHS in the UK. Individual modalities such as FES, TENS, EMG Biofeedback, strapping and motor relearning strategies for specific aspects of pain and tonal disturbances appear to have a part to play. Physiotherapy remains an intrinsic part of the rehabilitation strategy after stroke and it is the author's experience that our clients would like more! A considerable challenge remains for clinicians to further research this area¹⁴⁴.

KEY QUESTIONS FOR DISCUSSION:

- What is the incidence of spasticity and its best management in stroke patients of with different site and size of lesion?
- What is the relationship of overuse activity of the unaffected side of the body to spasticity and shoulder pain?
- To what extent is the cervical spine implicated in CRPS Type1/SHS?
- Does everything happen to severe stroke with combined paresis/cognitive deficits, ie.TACS?

Guideline topic: Evidence table covering: Frequency of hemiplegic shoulder pain – Appendix A				
Author	Year	Quality rating	Population Nos.	Outcomes Measured HSP Nos (%)
Van Owenaller ⁸	1986	IV	219	157 (72)
Bohannon ³¹	1986	IV	50	36 (72)
Bohannon ³⁹	1990	IV	24	17 (70)
Poulin de Courval ²⁷	1990	IV	94	45 (48)
Roy ⁷	1994	IV	76	55 (72)
Jespersion ¹⁶	1995	IV	173	38 (22)
Zorowitz ¹¹⁷	1996	IV	20	9 (45)
Wanklyn ²⁹	1996	IV	108	69 (64)
Gamble ²⁵	2000	IV	123	31 (25)
Ratnasabapathy ²⁸	2003	IV	1474 1336 1201	256 (17) at one week 261 (20) at one month 284 (23) at six months

Table 1

Guideline topic: Evidence table covering: Physiotherapy for hemiplegic shoulder pain – Appendix B								
Author	Year	Study type	Quality rating	Population	Intervention	Outcomes Measured	Confidence intervals/ p values	Comments
Tyson & Chissin ⁸²	2002	RCT	11b	22 stroke	Within-subject comparison of “axilla” hold vs “distal” hold	ROM of shoulder flexion using bubble goniometer & self-reported pain	Significantly better ROM using axilla hold P<0.001	Suggests proximal manual support results in greater painfree ROM
Dean et al ⁸³	2000	RCT	11a	28 stroke	Rehab programme plus prolonged positioning of the shoulder for 6/52 in the RX group	Resting Pain, pain on dressing, ROM – abd/lat rot	Differences between groups did not reach statistical significance p<0.05	Well-designed study – larger cohort planned
Lincoln et al ⁸⁴	1999	Single-blind RCT	11a	282 stroke	Three different: A Routine Physio B Plus expert Rx C Plus unqualified therapist	Assessment Battery: 12 validated tests designed to reflect impairment and disability parameters specific to the upper limb	No significant difference in the outcomes of the groups receiving increased intensity of physiotherapy Not specific to HSP	Well-designed methodologically sound study Comparison with other studies indicating positive results suggests levels of intensity and specifics of interventions and patient type may have been inappropriate

Guideline topic: Evidence table covering: Physiotherapy for hemiplegic shoulder pain – Appendix B								
Author	Year	Study type	Quality rating	Population	Intervention	Outcomes Measured	Confidence intervals/ p values	Comments
Sunderland et al ⁸⁵	1992	Single-blind stratified RCT	11a	132 stroke	Randomly assigned after stratification to receive: Conventional (67) or Enhanced Therapy (65)	Assessment Battery: Extended Motricity Index, Motor Club, Passive Movement and Pain, Frenchay Arm Test, 9-Hole Peg Test, Barthel ADL Scale	Enhanced therapy group achieved significantly better outcomes than conventional therapy with respect to strength, range and speed of movement. No difference in HSP was seen between the groups	Methodologically sound study Treatment effect small but statistically significant No effect on pain (ET group had more pain – Not Statistically Sig)
Kumar et al ⁸⁶	1990	Quasi-RCT	11b	28 stroke	Allocated to three different treatments: A: ROM by therapist (12) B: Skate board (8) C: O/H pulley (8)	Passive ROM Pain on rest and movement	No significant difference between groups 71% pain in overhead pulley group	Use of a pulley increases risk of developing HSP
Leandri et al ⁸⁷	1990:	Single blind placebo-control RCT	11b	60 strokes randomly assigned to 2 treatment groups (TENS) and 1 control	GroupA: high intensity TENS GroupB: low intensity TENS GroupC: placebo TENS All had physio	Passive range of shoulder motion	High intensity TENS achieved significant ↑ in shoulder passive ROM	Limited statistics available
Sonde et al ⁸⁸	1998	RCT	11a	44 stroke	Additional low TENS, 60 mins/day, 5 days per week, 3 months	Motor/ADL function, pain, spasticity	Low TENS Increases motor function p<0.01, but does not reduce pain or spasticity	
Sonde et al ⁸⁹	2000	Follow up study Case series	V	28 stroke from 44 above	No intervention	Motor/ADL function, pain spasticity	Rx effect lost – no significant difference between those in each group. Overall deterioration in all	
Partridge et al ⁹⁰	1990	Single-blind RCT	11b	85 stroke (20 lost during the study)	Cryotherapy vs physiotherapy Bobath Approach	Pain severity on movement, ROM lateral rotation	Bobath physiotherapy group reported less pain p<0.05	Suggests benefit of PT intervention

Guideline topic: Evidence table covering: Physiotherapy for hemiplegic shoulder pain – Appendix B								
Author	Year	Study type	Quality rating	Population	Intervention	Outcomes Measured	Confidence intervals/ p values	Comments
Inaba & Piorkowski ⁹¹	1972	Placebo control RCT	11b	33 stroke with HSP	Randomly assigned to: Group A (12): ROM/position Group B (10): Ultrasound plus exercise Group C: (10) As B with placebo ultrasound	Change in pain-free ROM at the shoulder	No significant difference between groups	Suggests U/S is not of benefit in the Rx of HSP
Williams et al ⁷⁵	1982	RCT with cross-over	11b	20 stroke with HSP	Conventional PT plus EMG biofeedback -Group 1 Plus relaxation - Group 2, then crossover	Pain McGill ROM Electrogoniometer	Pain reduced in both groups No significant difference between groups	Methodological issues
<p>Evidence Statement: there is weak evidence on the basis of some small treatment effects in some RCTs of variable methodological quality to support physiotherapy intervention in the management of HSP. The precise nature of the specific interventions is not well reported. Ultrasound does not appear to be of benefit. Overhead pulley exercise appears more likely to exacerbate HSP.</p> <p>Grade of recommendation: B</p>								

Table 2

Guideline topic: Evidence table covering: Evidence for physiotherapy for spasticity – Appendix C								
Author	Year	Study type	Quality Rating	Population	Intervention	Outcomes Measured	Confidence intervals / p values	Comments
Dvir & Panturin ¹⁰⁸	2003	Case control	1V	33 stroke	Bobath Physiotherapy	Spasticity and ARs using isokinetic dynamometry	Close relationship between spastic resistance and test angular velocity p<0.001	Reduction of spasticity with PT, but did not reach statistical significance
Sonde et al ⁸⁸	1998	RCT	11a	44 Stroke	Additional low TENS, 60 mins/day, 5 days per week, 3 months	Motor/ADL function, pain, spasticity	Low TENS Increases motor function p<0.01, but does not reduce pain or spasticity	
Sonde et al ⁸⁹	2000	Follow up study Case series	V	28 stroke from 44 above	No intervention	Motor/ADL function, pain spasticity	Rx effect lost – no significant difference between those in each group. Overall deterioration in all	

Bertrand & Bourbonnais ¹⁰⁹	2001	Controlled Trial	111	12 hemiparetic patients ?stroke 12 control	Isometric abduction of the hemiplegic upper limb	Orthogonal force and torque using force plate	Demonstration that hemiparetic patients generate less force with affected side than healthy controls	No randomisation No information on case mix
Bourbonnais et al ¹¹⁰	1997	Single case study	V1	34 year old PICH stroke patient	Motor re-education programme of increasing torque	Force measured using dynamometry	No increase in spasticity despite increasing levels of resistance	May suggest that resistive forces do not increase spasticity
Badics et al ¹¹¹	2002	Observe cohort – case series	1V	56 stroke	Resisted extension during WB of arm and leg	Spasticity Muscle strength	Strength increased, spasticity did not	No worse spasticity, but not reduced
Bate et al ¹¹²	1992	Observe cohort – case series	1V	16 stroke	Tracking visual target with EMG biofeedback from spastic antagonists	Measurement of tracking error using potentiometers	Reduced flexor activity during extensor activity in upper limb	Training did not improve movement control, despite reduction in flexor tone
Wolf et al ¹¹³	1993	RCT	11a	Stroke > 1 year ?no.	Training elbow extension with additional EMG biofeedback	Mean & Max EMG of triceps	Increased EMG activity in RX group p=0.05 Increased ROM in Rx group p=0.05	No change in flexor EMG suggesting better extensor activity, but no reduction in spasticity
Plant & Miller ¹¹⁴	1992	Observe cohort –case series	1V	15 stroke patients	Patients performed 2 manual tasks static & dynamic Mechanical stimulation of pectoralis maj & posterior deltoid	EMG activity of stimulated muscles measured	Amplitude of the stretch reflexes were comparable to those obtained during static contraction	Suggests that task specific activity with local inhibitory techniques can modify muscle tone

Evidence statement: the study designs used in the investigation of specific physical therapies for spasticity are insufficiently robust to support any intervention. Promising interventions include TENS and EMG biofeedback in the control of muscle tone.

Grade B

Table 3

Guideline topic: Evidence table covering: Evidence for shoulder Supports – Appendix D								
Author	Year	Study type	Quality Rating	Population	Intervention	Outcomes measured	Confidence intervals / p values	Comments
Rajaram & Holtz ¹²¹	1985	Case Series	V	20 stroke with UE pain	Sling consisting of shoulder and forearm support	Subluxation by X-ray Patient report of pain	Claimed 90% success	Unable to assess statistical effect
Brooke et al ¹²²	1991	Case Series	IV	10 hemiplegic patients with subluxation (6 stroke)	Comparison of three different supports in reducing subluxation	Radiographic reduction of subluxation	Harris Sling achieved best correction over Bobath cuff and Arm trough	Bobath Cuff caused some horizontal distraction of the shoulder
Zorowitz et al ¹²³	1995	Case Series	IV	20 Stroke patients <6 weeks post CVA	Comparison of four types of support in reducing subluxation	Radiographic reduction of subluxation	Single strap hemisling reduced subluxation vertically across entire group	Recommends trying different supports to achieve best reduction for that patient
<p>Evidence Statement: Although the relationship between shoulder pain and subluxation is not absolute, there is weak evidence and a clinical rationale behind the institution of shoulder supports as an adjunct to physiotherapy. The choice of support seems to depend on the patients' individual dimensions and shoulder alignment after stroke.</p> <p>Grade of recommendation: C and * Good practice point</p>								

Table 4

Guideline topic: Evidence table covering: Strapping of the hemiplegic shoulder after stroke - Appendix E								
Author	Year	Study type	Quality Rating	Population	Intervention	Outcomes Measured	Outcome Confidence intervals / p values	Comments
Hangar et al ¹²⁶	2000	RCT	IIb	98 Stroke 49 strapped/49 control	Shoulder strapping	Weeks 0, 6 & 14 VAS, SROMP, FIM, MAS, Rankin Disability	Strapped group had tendency to less pain on VAS p = 0.09	Good quality study with intention to treat analysis. Unclear as to intervention for prevention or treatment of HSP
Ancliffe ¹²⁷	1992	RCT - Pilot	IIb	8 Stroke 4Rx/4Control no voluntary upper limb movement	Shoulder strapping	Prevention HSP Modified RAI	Difference between days to develop HSP between Controls and strapped subjects p=0.01 – onset delayed	Small numbers single outcome measure
Morin & Bravo ¹²⁸	1997	Observe cohort	III	15 Stroke with subluxation	Shoulder strapping	Radiographic reduction in subluxation	Strapping reduces subluxation better than sling support p=0.01	Subluxation may not be related to pain. Pain was not considered
Herrmann et al ¹²⁹	1999	Observe Cohort - pilot	VI	5 Stroke	Shoulder strapping	Verbal rating scale	Reported significant reduction in pain – no statistics	Abstract – no details of intervention or analysis
<p>Evidence statement: Strapping the hemiplegic shoulder may reduce the onset and severity of HSP and reduce shoulder subluxation. Skin reactions and tissue viability may allow short-term use only. Further studies are required to determine the absolute efficacy of this intervention.</p> <p>Grade of recommendation: B</p>								

Table 5

Guideline topic: Evidence table covering: Physiotherapy interventions for Shoulder Hand Syndrome – Appendix F								
Author	Year	Study type	Quality Rating	Population	Intervention	Outcomes Measured	Outcome Confidence intervals / p values	Comments
Dirette et al ¹³⁶	1994	Case series		Stroke	CPM and elevation	Hand oedema, Finger stiffness		Study not seen
Giudice et al ¹³⁷	1990	Case series		Stroke	CPM and elevation	Hand oedema		Study not seen
Gracies et al ¹³⁸	2000	Crossover trial – case series	1V	16 Hemiplegic ? no. stroke 6 had swollen hands	Lycra garments designed as dynamic splints	Limb girth, spasticity, comfort/pain, ROM	Comfort was good, ROM improved, swelling decreased	
Roper et al ¹³⁹	1999	Single-blind RCT	11a	37 Stroke – controls had PT	PT plus Intermittent pneumatic compression of arm 50mm Hg	Hand volume by water displacement	No statistical difference between groups P<0.65	Well-designed methodologically sound study
Poole & Whitney ¹⁴⁰	1992	Expert opinion	V1	Not defined	Inflatable pressure splints	N/A	N/A	Subjective anecdote
<p>Evidence statement: Intermittent pneumatic compression is no more effective in reducing hand oedema than physiotherapy alone.</p> <p>Grade of recommendation: A</p>								

Table 6

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PHYSIOTHERAPY MANAGEMENT OF THE UPPER LIMB AFTER STROKE: RECOVERY AND TRAINING OF MOTOR FUNCTION (R9-B)

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INTRODUCTION

Rehabilitation of arm function following stroke is at present not adequate for many patients, since a significant number do not regain functional use of their hemiplegic upper limb¹. The purpose of this paper is to examine the evidence base for interventions that aim to improve motor function of the arm. The paper begins with a description of the motor deficit following stroke. These deficits in themselves suggest remedial treatments, and the treatments will be better understood if the deficits which they aim to improve are made clear. Evidence for different interventions is then presented. The review concentrates mainly on literature published in the last decade. Interventions include repetitive functional and strength training, constraint-induced therapy, robot-aided therapy, other specific treatments and particular treatment combinations. Functional electrical stimulation and pharmacological interventions have been omitted, as these are addressed elsewhere in this document. Evidence is presented in narrative form, with the addition of summary tables of evidence where the literature for an intervention was particularly large. Each paper relating to an intervention was rated according to the level of evidence table recommended by the organising committee² and inserted into tables of evidence or tables simply showing the rating. Difficulty was encountered in using the part of the rating scale concerning randomised controlled trials, because few papers defined a threshold clinically significant effect. Randomised controlled trials have therefore been rated II, except where a clinical threshold was defined, when IIa or IIb was applied. Grades of recommendation for groups of papers were assigned according to Shekelle et al³ based on the quality of the evidence, and not on a judgement of the effectiveness of the intervention itself.

1. CHARACTERISATION OF THE MOTOR DEFICIT

A. Decreased ability to generate force and spasticity

One of the most notable manifestations of a stroke is a decreased ability to generate force in muscles. Excessive antagonist activity has been suggested as one major cause of this, but several studies do not support this theory. Fellows⁴ examined the relationship between hypertonia and voluntary movement at the elbow of spastic patients as they moved against loads of 5 to 10% of the patient's maximum voluntary isometric torque. Maximum velocities during both elbow flexion and extension were reduced compared to normal, but during these movements made against a load, antagonist activity measured by EMG was at or below normal levels. Earlier studies support this view⁵⁻⁷. The main problem appears to be one of underactivation of muscles resulting from decreased cortical drive, with additional weakness developing over time with disuse.

Conflicting evidence exists on this issue. Kamper et al⁸ have recently shown that a degree of coactivation of finger flexors as well as decreased voluntary excitation of finger extensors prevent finger extension. In another study, subjects exhibited strong stretch reflexes during imposed finger extension movements at a constant velocity (shown by EMG and net work). Network of the finger flexors increased proportionally with velocity, demonstrating a contribution from spasticity. Most subjects did not have greater passive resistance to stretch than controls, so it was concluded that resistance to stretch was mediated primarily through neurological rather than biomechanical causes⁹. Spasticity has also been examined by passively stretching the elbow at different velocities by a torque motor¹⁰. The stretch reflex threshold was altered in subjects with spasticity, so it was suggested that rehabilitation might be most effective if it aimed to increase this threshold. Another study found a significant reverse correlation between spasticity and grip strength, and also between spasticity and Fugl-Meyer and Box and Block scores¹¹. However, the results were confounded by the use of the modified Ashworth scale to measure spasticity. This scale measures tone, defined as resistance to passive stretch and there are two contributing factors to an increase in resistance (hypertonus). These are changes to the passive length tension curve of the muscle from length-associated changes and neural changes associated with spasticity. The results of studies which measure clinical spasticity could be taken more seriously if spasticity was measured more directly, via displacement of the limb with a torque motor for example.

Associated reactions (non-purposive reactions triggered by voluntary movement¹²) have been examined by inducing them experimentally by a moderate or maximal contraction of the less affected arm. No correlation has been found between associated reactions and spasticity as measured by the Modified Ashworth scale¹³ and abnormal reflex activity¹⁴. One study also found no correlation between associated reactions and contracture. However, associated reactions tend to be present in more severely affected subjects and not in more moderately affected subjects¹².

B. Muscle strength distribution & grip force

The most comprehensive assessment of muscle strength in the arm after stroke remains a study by Colebatch and Gandevia¹⁵, who measured maximum voluntary strength of 12 muscle groups in the arm. Proximal groups were stronger than distal groups, not surprising given the innervation of proximal muscles from both hemispheres. The 4 strongest, in descending order, were elbow flexors, shoulder adductors, shoulder abductors and elbow extensors and the 3 most severely affected groups were those producing wrist and finger flexion. In contrast, more recent studies¹⁶¹⁷ have not found a greater weakness distally in the more

affected side (though one study¹⁶ found on the ipsilateral side, wrist extension was weakest, then shoulder abduction, then elbow flexion), though fewer muscles were tested. It is not clear whether each muscle was tested at a common proportion of its most lengthened position. This matters because the tension it is possible to generate changes with muscle length.

Stroke patients exhibit lower grip force ratios (paretic/non-paretic) than healthy subjects (dominant/non-dominant), and scale grip force in proportion to the maximal voluntary contraction¹⁸. Investigation of grip force in 2 stroke patients with cerebellar lesions, showed that force development was slowed and coordination of grip and lift force was impaired¹⁹.

C. Cognitive processing in purposeful movements

Reaching movements in patients with stroke are characterised by decreased velocity^{20 21}, increased segmentation of movements²¹, an increased path length of the hand trajectory²² and loss of interjoint coordination²³. Evidence of partial preservation of normal cognitive processing has been found. One group of patients retained the ability to coordinate grasp and transport at beginning of reach, adjust size of aperture according to object size and some interdependence between the two components remained²⁴. Scaling of movements to the object's distance may also be preserved²⁵. Reaching movements of patients with left hemisphere damage tend to lack coordination, whereas left brain damaged patients have difficulties in final approach to the object (hand ipsilateral to the lesion)²⁵. Another study identified problems with a tracking accuracy task, where unlike healthy subjects, patients did not improve their performance when presented with a stimulus-response compatible condition rather than an incompatible condition²⁶ (compatibility is the extent to which the stimulus matches expectations for correct response). Activation of prefrontal cortex may be important in relearning lost motor skills in stroke since fMRI measurements during finger tapping and handgrip showed that the activation volume in this area was significantly larger in stroke than healthy volunteers²⁷.

The role of contextual information in the performance of goal directed tasks after stroke has been explored. These studies demonstrate that reaching kinematics in patients with stroke became more like those of healthy subjects when an object was present and meaningful contextual information was provided²⁸⁻³⁰.

Motor deficits are also present on the side ipsilateral to the lesion, but these are relatively minor in comparison to the contralateral side and space does not allow these to be discussed further.

Compensatory movements in reach to grasp have been described³¹, but few have been properly measured. So far, these have concentrated on trunk flexion, which increases with decreased ability to perform elbow extension and shoulder flexion in the sagittal plane or in reaching movements across the body³²⁻³⁴. With trunk restraint, angles of elbow and shoulder motion increase and there is also a better temporal relation between joints³⁵.

These deficits in themselves suggest remedial treatments. These include increasing voluntary activation of agonist muscles, and increasing muscle strength, decreasing activity of the antagonist (less importantly), and normalising the cortical processes involved in generating and controlling arm movements.

D. Factors predicting recovery

Motor performance in early stages after stroke is a good predictor of recovery. Katrak et al³⁶ found that initial shoulder shrug and initial presence of synergic hand movement predicted good hand movement and function, at 1, 2 and 3 months. Active shoulder abduction also had some predictive value. Motor performance at 2 months was found to be a better predictor than initial motor performance in another study³⁷.

Lesion location is also an indication of recovery. Shelton and Reding³⁸ found the probability of recovery of isolated upper limb movements decreases progressively with lesion location as follows: cortex, corona radiata, posterior limb of the internal capsule (3% chance). Patients with purely cortical stroke were most likely to recover isolated movements (75% chance).

The Copenhagen stroke study^{1, 39} found that of 115 patients that 56% had non-functional arms at discharge from hospital. 39% of these improved in function, but this was by compensation with the less affected arm. It was concluded that no further recovery of the affected arm should be expected after 11 weeks, but motor impairment of the arm was not measured in any detail and the conclusion is at odds with other studies that have found good effects with interventions in chronic patients.

2. EVIDENCE FOR INTERVENTIONS

A. Repetitive practice

a) Repetitive functional training

Repetitive voluntary activation of muscles, without the assistance of robots, electrical stimulation or EMG biofeedback, has received much attention in the last decade. In a systematic review, van der Lee et al⁴⁰ identified thirteen randomised controlled trials investigating the effectiveness of exercise therapy after stroke. A definitive conclusion could not be drawn about the effectiveness of exercise therapy. However, in five of the six studies that reported positive short-term results on an arm function test, there was a greater amount or duration of exercise therapy in the experimental group, suggesting that more intensive exercise therapy is beneficial. Tasks in these studies varied and included increased amounts of practice with techniques to facilitate learning of motor skills⁴¹, functional exercises that facilitated forced arm and hand activity⁴², constraint-induced therapy^{43 44} and robot-aided therapy⁴⁵.

Three other studies with a contrast in amount or duration of therapy did not show positive short-term effects^{46 47 48}. However, one of these studies in which subjects practised pushing movements with the arm extended within an in-

flatable splint and wrist dorsiflexed⁴⁶ showed a significant effect at 6 month follow-up. Another study, where more treatment was given according to usual British practice (Bobath approach, with some influence of movement science-based approaches) delivered by a trained assistant⁴⁹ showed significant positive effects of 10 hours extra physiotherapy for the arm for a subgroup of less severe patients. Three of the studies with positive short-term results still showed positive effects at a follow-up of six weeks⁴², one year⁴³ or two years⁴⁴. Table 1 shows a summary of the trials in the systematic review and the additional trials to be described here.

The remaining studies in the review that did not show positive effects involved home-based exercise⁵⁰, neurodevelopmental technique versus traditional functional retraining⁵¹, sensorimotor integrative treatment versus functional treatment⁵² and facilitation versus traditional techniques. The sixth study to show positive effects involved use of a mirror in training⁵³.

A recent randomised controlled trial⁵⁴ not included in the review found a positive effect for a programme of 15 extra practice sessions, lasting 30 minutes or less for subjects who could move arms against gravity and grip objects. Training consisted of eight different tasks with graded difficulty, including activities such as turning coins and placing large and small objects. Subjects receiving arm ability training improved in the mean time needed to perform tasks and the time taken to do the first ballistic component of aimed movements.

Two meta-analyses investigating effects of intensity of rehabilitation have demonstrated a statistically significant summary effect size for activities of daily living, neuromuscular, functional outcome variables⁵⁵ and mortality⁵⁶. Greater intensity of rehabilitation is likely to include more repetition of functional tasks, so these results indirectly support repetitive practice. The Royal College of Physicians Clinical Guidelines for Stroke point out that interpretation of some trials of contrasting intensity are confounded because services giving more therapy were usually also well organised and expert, in comparison with the control group.

(b) Repetitive strength training

Three trials using a multiple baseline design have tested the effect of repetitive strength training, using biomechanical parameters and the Rivermead Motor Assessment. In the first study⁵⁷, 27 patients 3-19 weeks after stroke, underwent a baseline phase of physiotherapy according to the Bobath concept lasting between one and three weeks, followed by a variable number of weeks of a program of twice daily 15 minute training sessions consisting of repetitive hand and finger flexions and extensions against various loads. Patients receiving the strength-training program significantly improved in grip strength, peak force of isometric hand extensions, peak acceleration of isotonic hand extensions and contraction velocities, in comparison to the group receiving baseline physiotherapy throughout. A control condition of TENS treatment also resulted in no significant changes.

A second study closely replicated the strength training program in the previous study and compared it to EMG triggered electrical stimulation⁵⁸. Twenty patients, 2-24 weeks after stroke underwent a 2 week baseline phase, followed by 2 weeks of stimulation, followed by 2-4 weeks of repetitive strength training. Patients in these studies all had at least some finger and hand movement. Both intervention phases involved 20 minute sessions twice a day. There was no significant change in the baseline phase, but a significant improvement in both intervention phases, with neither being more effective than the other.

A third study⁵⁹ compared suprathreshold electrical stimulation (no voluntary contraction) with the repetitive strength training program in a multiple baseline design with twelve patients, 3-14 weeks after stroke. There was a significant change during the strength-training phase but not the stimulation phase.

In a further randomised controlled trial, a 10 day isometric power training program for hand flexion and extension (in addition to usual therapy) was compared to no extra therapy⁶⁰. There was a significant improvement in strength measured with a hand and finger dynamometer in the experimental group, but not in the control group. Another program that aimed to increase arm strength by arm presses, saw an increase of 40% in supporting arm strength after 4 weeks of training⁶¹. This trial was not randomised and measurements before and after training were compared. Extent of strength gain correlated with intensity and number of exercising units.

Four of these studies assessed tone weekly or before and after intervention using the modified Ashworth scale⁵⁷⁻⁵⁹. All found tone did not increase due to strength training and one found a decrease⁵⁹. This is relevant clinical point because it is contrary to the expectation based on the Bobath concept that rapid and vigorous contractions lead to an increase in muscle tone.

Neurophysiological research also indicates that repetition is important for motor learning. Intensive training of manual skills in monkeys, after a small cortical lesion in the hand region of sensory or motor cortical areas, leads to the appearance of new areas of digital representation in the undamaged tissue surrounding the lesion⁶²⁻⁶⁴. Studies in healthy human subjects have suggested that motor cortical areas are modifiable as a result of skill learning⁶⁵⁻⁶⁷. Remodelling of sensory and motor areas has been shown to depend on practice⁶⁸. The daily practice of specific tasks in this neurophysiological research far exceeded the total therapy time of about 45 minutes allocated to stroke patients in a specialized stroke care unit⁶⁹.

Other therapies, including robot-aided therapy and constraint-induced therapy also contain an element of increased amount of practice and these studies will be evaluated later in this paper.

EVIDENCE STATEMENT

A considerable number of trials, containing a range of interventions, support the notion that more intensive practice is beneficial to stroke patients and the repetitive element of practice is an important factor. The amount of extra practice

required to have a significant effect on outcome is between 15-40 minutes per day for at least several weeks (Table 1). Most studies included patients with a range of mild to severe deficits. Future trials are needed to determine the effectiveness of different types of exercise therapy/practice for patients with different levels of arm motor deficit.

Grade of recommendation – A

B. Constraint-induced therapy

This therapy originated in experiments with deafferented monkeys who had developed learned non-use of the affected arm after initial attempts to move the arm failed. Applying a constraint to the unaffected arm was found to have the effect of allowing the monkeys to relearn to use the affected limb to retrieve food. Taub and colleagues⁴⁴ examined the effect of applying a constraint to the intact limb of patients with stroke in a randomised controlled trial. Nine subjects at least one year after stroke were assigned either to a group receiving constraint by means of a resting hand splint and sling for 90% of waking hours, for 14 days, whilst undergoing 6 hours of practice 5 days per week, or an attention comparison group. The experimental group was significantly better on outcome measures of motor function and use in everyday activities. The amount of practice differed substantially between the groups, so it was not clear whether it was the restraint alone, practice alone, or the combination, which caused the effect.

Another randomised controlled trial was conducted afterwards by van der Lee et al⁴³, where the practice and therapist attention, was the same in both groups except that the control group used both arms. The treatment for both groups was 6 hours a day, for 2 weeks, 5 days a week. A significant difference in effectiveness was found in favour of the constraint group for the Action Research Arm test and the amount of use. Two recent case reports have demonstrated similar results with the same dose of therapy as in Taub's original experiment^{44 72 73}. A further randomised controlled trial⁷⁴ found that significant differences could still be obtained when practice was reduced to 3 hours per day, though gains were not as great as with 6 hours. Improvement was also obtained in a case report with the constraint applied for 5 hours per day for 10 weeks plus one hour of therapy 3 times per week⁷⁵.

Miltner et al⁷⁶ employed a design in which patients were tested before and after constraint-induced therapy. There was no change in baseline, but significant changes occurred in motor function and amount of use after treatment and were sustained at 6 month follow up. Sub acute patients did as well as chronic patients. Patients in the all studies above were required to have at least 10° voluntary finger extension and 20° wrist extension. A case report by Crago et al⁷⁷ has shown that a patient with less ability (10° extension of only 2 fingers and 10° wrist extension) can achieve comparable changes to more able subjects. A summary of evidence from constraint-induced studies is presented in Table 2. The mechanism at work is not yet clear. Unmasking of suppressed motor activity may be responsible as suggested by Taub et al⁴⁴ or neural reorganisation may be involved.

EVIDENCE STATEMENT

Constraint-induced therapy is effective in improving motor function and amount of arm use in chronic patients, when combined with intensive practice of functional activities. Although 6 hours practice has usually been employed, effects are still obtained with 3 hours. Further research is needed to determine whether it may also have benefits for more acute patients. Neurophysiological studies will be useful to help determine the changes that occur in the central nervous system as a result of the therapy.

Grade of recommendation – A

C. Robot-aided training

Robotic applications to rehabilitation of stroke patients have been described^{78 79}. Sophisticated robotic aids can substitute for the affected hand, adapt to intermediate levels of ability, or adjust to not help when the arm is fully recovered⁸⁰. They can support and enhance the clinician's efforts. Robot-aided classes and home-therapy with telerehabilitation are envisioned. Robots currently aid exercise of shoulder and elbow movement, rather than movement of wrist and fingers. The robot can also provide measures of position, velocity and forces applied. The MIT-MANUS robot⁷⁹, designed for clinical neurological applications, has been tested in two studies. In one⁸¹, 20 patients, 3 weeks after stroke, were stratified on the basis of motor impairment to either robot-assisted therapy or sham robot-assisted therapy. All patients had conventional therapy and the experimental group also had 4-5 hours of robot-aided therapy per week with MIT-Manus. Visual feedback of movements was provided. Tests used, administered by a blind assessor, were the Functional Independence measure (FIM), Fugl-Meyer (F-M), motor power and MSS – a motor status scale designed to increase the number of isolated muscle groups assessed. There was a significantly greater change on MSS for the robot group, and a trend to better motor power and scores on the proximal section of the F-M. Volpe et al⁴⁵ reported that the outcome was sustained 3 years later.

Training with a robot called MIME has been compared to neurodevelopmental therapy in a randomised controlled trial⁸² with 27 patients. The robotic group received 24 x 1 hour sessions over 2 months of robot-assisted shoulder and elbow movement and the neurodevelopmental treatment (also 24 x 1 hour) concentrated on proximal function. The robot group performed significantly better on the F-M at 1 month, on the F-M, reach extent and isometric strength at 2 months, and on the FIM at 6 months. Another randomised controlled trial has been recently reported in abstract form⁸³, comparing sensorimotor and robot-aided therapy. Significant results were found on the F-M, MSS and MRC power score in both treatment groups.

EVIDENCE STATEMENT

Two trials have shown superior outcomes for robot-aided therapy compared to 'sham' robot therapy and neurodevelopmental treatment, on some measures. Although research into this intervention has just begun, this appears to be a promising prospect as it offers opportunities also for in-

creasing the amount of practice and giving knowledge of results to patients.

Grade of recommendation - B

3. OTHER SPECIFIC TREATMENTS

There is little research into the effectiveness of specific elements of what might be called 'ordinary' physiotherapy, apart from the repetitive element described above. One case report investigated the effect of passive accessory joint mobilisation⁸⁴. Grade IV oscillations were performed for 30 minutes, twice a week at the shoulder, elbow, wrist, hand and finger joints, for 6 weeks. Range of movement improved markedly at all joints. However, stretching, range of movement exercise, PNF, home exercise and functional activities were also administered, so the improvement was not entirely attributable to the mobilisation. A home programme of stretch (5 minutes/day), weight-bearing with splint, and finger extension exercise, was combined with injection of botulinum toxin into spastic long finger flexors, in 14 chronic stroke patients, in an uncontrolled study⁸⁵. Significant changes in tone and finger extension 1 week after injection did not last. Chronic patients are likely to have length-associated changes in muscle (in sarcomeres and connective tissue), which would require a longer stretch to overcome⁸⁶.

Evidence that both arms are constrained to behave as co-ordinated units during bilateral performance of the upper limbs^{87 88} suggests that bilateral simultaneous practice might drive the activity of the hemiplegic arm by employing undamaged parts of the brain. Mudie et al⁸⁹ conducted some elegant single case experiments to evaluate the effects of bilateral simultaneous practice. This type of practice was compared with unilateral practice or bilateral practice with hands linked, in eight, single case, multiple baseline studies. Unilateral performance with the hemiplegic arm was evaluated during block placement, simulated drinking and moving pegs to eye level, by blind, standardized observational kinematic analysis over 4 phases of 10 daily sessions. Improvements were statistically superior to the negligible effects of unilateral or hands linked conditions and persisted at 6 month follow up. The measurements could have been improved by employing more accurate three-dimensional motion analysis, but the approach was very thorough and the results convincing. Two further studies provide support for bilateral training^{90 91}.

Various types of orthoses have been tested. Good effects of wearing cuffs on the arm made of lycra with plastic boning⁹² or spandex reinforced elastic bandage materials⁹³ have been found. A case report⁹³ showed an increase in elbow range of movement and a cross-over design⁹² reported improved wrist posture, reduction in wrist and finger flexion spasticity, reduced swelling in patients with swollen limbs, and an improved passive range of movement at the shoulder after a 3 hour period of wearing the garment. Hand, wrist and airsplints have been described but little evidence was available on their efficacy. Aims of applying resting splints include maintaining passive stretch in a functional position and reduction of tone⁹⁴. The aims

of using inflatable pressure splints are to reduce tone, facilitate muscle activity around a joint, increase sensory input, control oedema and reduce pain⁹⁵.

Virtual reality-augmented rehabilitation is a relatively new intervention and at this stage, case reports were available^{96 97}, but not controlled trials. In training exercises, the patient wore one of two different types of gloves – one for monitoring amplitude, speed and fractionation of movement, the other, a force feedback glove, monitoring strength of finger flexion and extension movements. Monitoring was achieved by infrared sensors and force transducers within the gloves. Online visual, auditory and force feedback was provided via a personal computer. Exercises were in the form of imaginative computer games with graphics feedback and goals were set according to ability. One and a half hours of virtual reality training plus practice of fine motor tasks, spread over a period of 3.5 hours per day for 2 weeks was found to have good effects. There is scope for providing a greater amount of training than patients usually have, as the patient can practice at home and have their progress monitored remotely by a therapist via the web. It appears novel and motivating. A similar type of web-based telerehabilitation has been described⁹⁸, which aims to provide low cost, intensive, repetitive practice of functional movements via input devices such as a force feedback joystick and traditional mechanical mice, or gyroscopic or force feedback mice.

Response to training with EMG biofeedback has been thoroughly investigated. Tables of evidence from the Royal College of Physicians Clinical Guidelines for Stroke identify 3 meta-analyses⁹⁹⁻¹⁰¹ and 9 randomised controlled trials¹⁰²⁻¹⁰⁹. Only two of these have shown significant positive effects of EMG biofeedback for the arm¹¹⁰, (one of these was combined with muscle stimulation), and an additional two showed minor effects. The randomised controlled trial by Crow et al¹¹⁰ and another not included in the clinical guidelines¹¹¹ are the two trials to have shown positive effects^{110 111}. Both studies used biofeedback to increase active movement, and one also used it to reduce tone¹¹⁰. Between group comparisons were significant in favour of the experimental group for arm function tests in one study¹¹⁰ and in the other there were significant increases in EMG measures of triceps activity for the experimental group only, though between group comparisons were not significant. Bate and Matyas¹¹² investigated the effect of a single session of EMG biofeedback of elbow flexor activity, delivered whilst tracking a sinusoidal target by flexion and extension movements of the elbow. There was actually a negative transfer effect for the experimental group in this randomised trial compared with the control group (no biofeedback) when tested in slightly different tracking conditions after the session. There was a trend towards greater reduction in elbow flexor activity in the experimental group, but this clearly had no effect on ability to perform the elbow movements, supporting the findings of a previous study¹¹³ with patients with cerebral palsy, who were also able to reduce elbow flexor activity, but with no effect on function.

Exploratory work with positive results is also occurring with rhythmic cueing via a metronome to improve spatiotemporal patterns of arm movement¹¹⁴ and intensive finger tracking practice to improve grasp and release¹¹⁵. For specifically increasing the supination movement of the forearm, a functional task (e.g. tipping dice) has been found more effective than simply rotating the forearm¹¹⁶. Table 3 shows the ratings for studies not included in tables of evidence.

EVIDENCE STATEMENT

There is little evidence to support the specific treatments described above. In most cases this is because there is insufficient data available at the present time. Results indicate that bilateral simultaneous training and virtual reality and telerehabilitation may be promising interventions. EMG biofeedback has been thoroughly investigated compared to other specific interventions, with mostly negative results.

Grades of recommendation:

B (bilateral simultaneous training)

A (EMG biofeedback)

C (other specific interventions)

4. COMPARISONS OF TREATMENT COMBINATIONS

Physiotherapeutic approaches to the treatment of stroke patients include the Bobath (neurodevelopmental), Movement Science (motor relearning), Brunström, PNF, Rood, Affolter and sensory integration approaches. Comparisons of Bobath, proprioceptive neuromuscular facilitation, Rood and □conventional□ treatments¹¹⁷⁻¹¹⁹ have shown no significant differences in outcomes. These trials have been criticised for lacking key requirements of a well-controlled study including evaluation by a blind assessor, randomisation and sample sizes determined by power calculation, for late intervention of too short duration^{120, 121} and using measures not specific to motor impairments. In a single case experimental design comparing neurodevelopmental and Brunströmm treatment, walking speed improved more in the Brunströmm treatment for only one out of seven patients, but this result did not generalise to other gait parameters or upper arm function measures¹²². A controlled, non-randomised study (124 patients with acute stroke) found similar disability and placement outcomes, but a 25% shorter length of stay for a unit with a functionally oriented approach compared with a unit using an impairment-focused approach¹²³.

Bobath based treatment^{124 125} and a framework based on the movement sciences ('motor relearning'), outlined by Carr and Shepherd^{31 126} were compared in a randomised controlled trial with 61 patients¹²⁷. In contrast to some earlier studies, this trial was randomised, used a blind assessor, included impairment measures, determined sample size by power calculation and treatment began early and was continued for as long as the patient was hospitalised. There were significant differences between the treatments in length of stay and a higher summed Motor Assessment

Scale score and a higher score on the arm section of the Sødning Motor Evaluation scale at 2 weeks in favour of the motor relearning group. However, comparison of outcome did not correct for initial status regarding motor function in the groups which descriptive measures showed to be better for the motor relearning group. Updated versions of these two treatments have also been compared in a randomised controlled trial with 120 patients, led by the author (unpublished data, 2003). No significant differences were found. Treatment was started earlier and was more intensive in the previous study (40 minutes compared to 23 minutes per day). It may be the combination of early, more intensive treatment with the Motor Relearning principles that is more effective.

Two other studies have investigated the Bobath concept. In a single group study with 33 patients¹²⁸, the effectiveness of 4 weeks of one hour sessions 3 times per week of Bobath treatment was evaluated by measuring spasticity with the Kincom dynamometer (passive mode) and associated reactions with a goniometer. There was no significant difference before and after treatment, but a tendency for spasticity to reduce. Hummelsheim et al¹²⁹ tested the idea used in Bobath treatment, that different body positions could alter tone. No effect of three 3 different body positions was detected (supine with hands by side, supine with shoulder abduction and elbow extension, sitting with both arms relaxed) on transcranially evoked potentials in biceps and abductor pollicis brevis muscles of 32 stroke patients.

It is surprising that despite the fact that treatments such as Brunström and Bobath were developed some time ago, before much of the scientific information of today became available, and that there is no evidence for their superiority, numerous investigative studies use the principles of these methods as their starting point. This is reflected also in the wide use of the Fugl-Meyer scale, which was based on the Brunström method. The Movement Science based framework is rarely mentioned, even when summaries of current physiotherapy treatments are given, despite the existence of published information since 1984. Table 4 summarises studies comparing the different treatment combinations.

EVIDENCE STATEMENT

The motor relearning (movement science) approach alone has shown superior effects, in a single trial. Comparisons of whole treatment combinations are necessary to show the effect of the interaction of elements of therapy. More, well conducted randomised controlled trials are needed to establish the best treatment combination, greater intensities of treatment should be included and multicentre trials should be considered to increase power. It is also recommended that elements of treatment with proven efficacy, should be combined into a whole¹³⁰ and this tested against usual rehabilitation

Grade of recommendation - B



CONCLUSION

Research into physiotherapy management of restoration of upper limb motor activity after stroke has progressed considerably during the last decade. We have learned that effective intervention is likely to include intensive practice of functional movements and movement components, and incorporate adjuncts to treatment such as constraint-induced therapy when appropriate. However, there is much still to be learned. This is reflected by the absence of Cochrane reviews on this topic.

From this review and the author's knowledge of clinical intervention, several areas have been identified where further research is required because of insufficient or absent evidence:

- Best interventions for different level of impairment
- Best combination of interventions
- Constraint-induced therapy for acute patients
- Bilateral simultaneous training
- Robot-aided therapy
- Virtual reality training
- Telerehabilitation
- Movement Science (motor relearning) therapy
- Normalising the cortical processes involved in purposeful movements
- Practice schedules (e.g. blocked, random, constant varied)
- Feedback (e.g. knowledge of results, knowledge of performance, timing and frequency of feedback)
- Manual guidance
- Practice of specific movements (e.g. shoulder external rotation)
- Passive accessory joint mobilisation
- Prolonged muscle stretches

KEY QUESTIONS:

Which physiotherapy interventions are most effective for patients with different levels of ability?

How can motor learning principles be incorporated into future research to improve effectiveness of interventions?

What is the best approach to identifying and testing the effectiveness of components of routine physiotherapy exercise training, (e.g. different exercises for training shoulder flexion, or external rotation)?

How can information about efficacy of treatments be best disseminated to clinicians?

Author, year	Design & subjects	Rating of study design	Interventions	Main outcome measures	Results
Sunderland 1992 1994	65 E / 67 C Acute (median 8-10 days) Inability to complete 9 hole peg test < 18 s	II	E Enhanced therapy C Conventional therapy E more than twice the amount of arm therapy per week, over a longer period. Included techniques to promote skill acquisition	EMI Subtests of Motor Club Assessment Frenchay Arm Test Nine-hole peg test Barthel	Small but statistically significant difference in favour of E group after 6 months for all measures except Frenchay; effect concentrated in mild patients; effect lost at follow-up
Kwakkel 1999	33 E / 37 C Acute (mean 7.2-7.5 days) Median ARAT: 0	II	E half an hour extra arm training, 5 times/week for 20 weeks + basic rehab programme C half an hour immobilisation of arm and leg by aircsplints, 5 times/week for 20 weeks + basic rehab	ARAT (dexterity) Barthel	Significant difference in favour of E group only in ARAT.
Feys 1998	50 E / 50 C Acute (mean 2.4-24 days) F-M < 46 Mean 14	II	E Inflatable arm splint, arm used to push backwards repeatedly while on rocking chair + usual rehab C Fake short-wave diathermy on rocking chair + usual rehab Both interventions for 30 mins/day for 6 weeks	F-M ARAT Barthel	Significant difference in favour of E only at 6 month follow-up, on F-M
Lincoln 1999 Parry 1999	94 E QPT 93 E APT 95 C Acute (1-5 weeks) Median ARAT: 0		E 2 hours/week additional from QPT or APT for 5 weeks + daily routine PT C Daily routine PT	RMA arm section ARAT Ten hole peg test Grip strength BI Extended ADL scale	No significant effect for whole group. Significant effect for mildly impaired subgroup in favour of E APT compared to both other groups on ARAT. Also significant effect for this group on RMA in comparison to C, which was sustained at 6 months.
Werner 1996	28 E / 12 C Chronic (mean 2.9 (E) and 3.3 (C) years) Initial (mean?) FIM-MM 70 (C) to 75 (E)	II	E 1 hour PT and 1 hour OT on 4 days/week for 12 weeks C no treatment	FIM-MM Jebsen hand function test	Treatment had a lasting effect
Duncan 1998	10 E / 10 C Sub acute (66 (E) and 56 (C) days) Mean FMA 37	II	E - home-based exercise programme for 1.5 hours 3 times/week for 8 weeks C usual care: variable content, frequency (average 39 visits in 12 weeks) and duration (average 44 minutes)	FMA Jebsen hand function test Barthel Lawton IADL MOS-36	No significant differences in upper extremity functional performance
Gelber 1995	15 E / 12 C Acute (11.3 (E) and 13.8 (C) days) Residual arm function	II	E neurodevelopmental technique, frequency/duration not stated C Traditional functional retraining, frequency/duration not stated Interventions for duration of inpatient and outpatient rehabilitation	Length of stay Total inpatient rehabilitation costs FIM Time to ADL milestones Box & block test Nine-hole peg test	No significant differences in effectiveness



Author, year	Design & subjects	Rating of study design	Interventions	Main outcome measures	Results
Jongbloed 1989	43 E / 47 C Sub acute (average 40 days) Brunströmm stage 1-5	II	E sensorimotor integrative treatment C Functional treatment 5 times/week 40 minutes for 8 weeks	Barthel Meal preparation 8 subtests of Sensorimotor Integration Test battery	No statistically significant differences between two groups
Altschuler 1999	4 E first: 5 C first (crossover design) Chronic (mean 4.8 years) Mild to extremely severe	II	E symmetric movements using a mirror C symmetric movements using a transparent plastic sheet 15 minutes twice/day, 6 days/week for 4 weeks	Subjective comments from patients Rating of improvement based on video-tapes of 'cardinal movements of the upper limb'	'Mirror therapy may be beneficial for at least some patients'
Platz 2001	20 E arm ability training 20 E arm ability training + knowledge of results 20 C Acute (mean E 6.1, E+KR 6.2, C 10.3) Mild impairment (MI arm score < 100)	II	E arm ability - eight different arm tasks with graded difficulty+ routine therapy 32 minutes or less/day for 3 weeks E arm ability + KR -as above + KR + routine therapy C - routine therapy	TEMPA Kinematic analysis: Total MD Duration of ballistic component Duration of maximum deceleration to end	Subjects receiving arm ability training improved significantly more in mean time needed to perform tasks and the time taken to do the first ballistic component of aimed movements, compared to both other groups. 1 year later, differences in TEMPA sustained.
Lippert-Gruner 2000 (Abstract)	20 Sub acute (4-6 weeks)	II	E - 10 day program of hand flexion and extension training with dynamometer + usual rehabilitation C usual rehabilitation	Maximal power values	Significant improvement in E, but not in C, over time
Butefisch 1995	27 Multiple baseline design across individuals Subacute 3-19 weeks Ability varied between minimal movement and minimal deficit	IV	Baseline 1-3 weeks of routine physiotherapy according to Bobath concept, followed by variable number of weeks of a program of twice daily 15 minute training sessions consisting of repetitive hand and finger flexions and extensions against various loads. 15 patients randomly assigned to receive 2 weeks of TENS after baseline and before repetitive training.	Grip strength Peak force of isometric hand extensions Peak acceleration of isotonic hand extensions Contraction velocities	Patients receiving the strength-training program significantly improved in grip strength, peak force of isometric hand extensions, peak acceleration of isotonic hand extensions and contraction velocities, in comparison to the group receiving baseline physiotherapy throughout. Control TENS condition treatment resulted in no significant changes.

Author, year	Design & subjects	Rating of study design	Interventions	Main outcome measures	Results
Hummelsheim 1996	20 patients Multiple baseline across individuals Subacute 2-24 weeks MCA stroke Ability varied between minimal movement and minimal deficit	IV	2 week baseline, followed by 2 week period of EMG-initiated stimulation (extensor and flexor muscles of hand) then 2-4 weeks repetitive training as in Butefisch. Both interventions 20 minutes twice daily Repetitive training programme included grip strength training, rapid isotonic and isometric wrist extension against weights.	RMA arm section, Modified Ashworth. Biomechanical parameters.	Biomechanical parameters and RMA – no change in baseline, but significant change in both other phases. Neither intervention found to be best. Best results with those with more movement at beginning. No significant change in tone. Patients preferred repetitive training.
Hummelsheim 1997	12 Multiple baseline design across individuals Sub acute 3-4 weeks MCA stroke	IV	Baseline 1-3 weeks, followed by 2 weeks of suprathreshold stimulation (no voluntary contraction), then 2 weeks repetitive training as in Butefisch.	Rivermead arm section, Modified Ashworth. Biomechanical parameters.	No significant change in baseline. Significant change in repetition phase but not stimulation phase, for all measures.
Badics 2002	56 3 weeks – 10 years Muscle power 3-4 on British MRC scale	VI	4 week program for supporting strength of arms by arm presses and leg strengthening exercises.	Muscle strength, Ashworth scale.	Significant increase in supporting strength of UL (40%). Extent of strength gain correlated with intensity and no. of exercising units.

N. B. Some information has been obtained from van der Lee ⁴⁰.

E – Experimental group; C – Control group; EMI – Extended Motricity Index; ARAT – Action Research Arm Test; F-M – Fugl-Meyer assessment scale;

RMA – Rivermead Motor Assessment; QPT – Qualified physiotherapist; APT – Assistant physiotherapist; FIM-MM – (Functional Independence measure)

Motor Measure; FMA –upper extremity motor section of the Fugl-Meyer assessment scale; MOS-36 – Medical Outcomes Study-36 Health Status Measurement; KR – knowledge of results; TEMPA – Test Evaluant les membres superieurs des personnes Agees (timed test of upper extremity performance of tasks representing ADLs); MRC – Medical Research Council.

Table 1 Table of evidence of the effect of repetitive functional and strength training (excluding constraint induced and robot-aided therapy). Studies are listed in order of rating.

Author, year	Design & subjects	Rating of study design	Interventions	Main outcome measures	Results
Taub 1993	4 E / 5 C Chronic (> 1 year) At least 10° voluntary finger extension and 20° wrist extension	II	E Constraint-induced therapy with resting splint and sling, 90% waking hours + 6 hours practice/day for 14 days C Attention comparison – procedures to focus on arm	Emory Motor Function test Arm Motor Activity test MAL	Significant difference in favour of experimental group on all measures. Motor Activity Log result maintained at 2 year follow up.
Van der lee 1999	31 E – constraint 31 E – bimanual Chronic (median 3.4 and 2.7 years) At least 10° voluntary finger extension and 20° wrist extension	IIB	E Constraint-induced therapy with splint and sling + 6 hours practice/day, 5 days/week for 2 weeks E Bimanual therapy 6 hours practice/day, 5 days/week for 2 weeks	RAP ARAT F-M AL	Significant difference in favour of the constraint group on ARAT and Motor Activity Log. ARAT results sustained at 1 year follow up.
Sterr 2002	8 E- 3 hour constraint 7 E – 6 hour constraint Chronic (mean 4.8 years) At least 10° voluntary finger extension and 20° wrist extension	II	E 3 hour: Constraint-induced therapy with resting splint and sling, 90% waking hours + 3 hours practice/day for 14 days E 6 hour: Same as above for 6 hours	WMFT MAL	Significant changes in both measures in both groups, significantly greater in 6 hour group.
Miltner 1999	15 chronic (mean 5.1 years).	VI	Constraint-induced therapy with resting splint and sling, 90% waking hours + 6 hours practice/day for 14 days	WMFT Arm Motor Ability test MAL	No change during baseline. Significant change in MAL and WMFT after treatment, sustained at 6 month follow up
Kunkel 1999	5 chronic (median 6 years)	VI	Constraint-induced therapy with resting splint and sling, 90% waking hours + 6 hours practice/day for 14 days	Actual amount of use test MAL WMFT Arm Motor Ability test	All tests showed significant improvement
Blanton 1999	1 subacute (4 months)	VI	Constraint-induced therapy with mitt, 90% waking hours + 6 hours practice/day for 14 days	WMFT MAL	Improved on both measures and maintained at 3 month follow up
Page 2002	1 chronic (2.3 years)	VI	Constraint applied for 5 hours/day for 10 weeks and one hour of therapy 3 times per week	F-M ARAT MAL	Improved on all measures (only one statistical test, on MAL, which was not significant)
Crago 2000	1 chronic (6 years) 10° extension of only 2 fingers and 10° wrist extension	VI	Constraint-induced therapy with mitt, similar practice schedule to previous trials for 3 weeks	Amount of use WMFT MAL	Improved on all measures

E – Experimental group; C – Control group; MAL – Motor Activity Log; RAP – Rehabilitation Activities Profile; ARAT – Action Research Arm Test;

Table 2 Table of evidence of the effect of constraint-induced therapy.

Author, year	Rating	Author, year	Rating	Author, year	Rating
Schleenbaker, 1999	I	Hurd, 1980	II	Cunningham, 2002	V
Moreland, 1994	I	Inglis, 1984	II	Whitall, 2000	V
Glanz, 1995	I	Wolf, 1994	II	Winnege, 2002	VI
Lum, 2002	II	Crow, 1989	II	Rodriquez, 2000	VI
Fasoli, 2002	II	Nelson, 1996	II	Mudie, 1996	VI
Lee, 1976	II	Bate, 1992	II	Gracies, 2000	VI
Bowman, 1979	II	Carey, 2002	II	Neeman, 1992	VI
Smith, 1979	II	Aisen, 1997	III	Jack, 2001	VI
Greenberg, 1980	II	Volpe, 2000	III	Merians, 2002	VI
Prevo, 1982	II	Thaut, 2002	V	Reinkensmeyer, 2002	VI

Table 3. Ratings of intervention studies not included in tables of evidence 1, 2 and 4.

Author, year	Design & subjects	Rating of study design	Interventions	Main outcome measures	Results
Langhammer 2000	33 E Motor relearning 28 E Bobath Acute (3 days)	II	40 minutes/day for duration of rehabilitation	MAS Sødring Motor Evaluation scale Barthel	Significant differences in summed MAS, arm section of Sødring in favour of Motor relearning group at 2 weeks. Shorter length of stay for Motor relearning group.
Loggigian 1983	42 randomly assigned to Conventional or Bobath/Rood Acute/subacute (within 7 weeks)	II	Continued until functional and motor performance stabilised	Barthel Manual muscle test	No significant differences between groups
Dickstein 1986	57 E Conventional 36 E PNF 38 E Bobath Quasi-randomized Acute (16 days approx.)	III	6 weeks of intervention for each group 30-45 mins/day	Barthel AROM Muscle tone	No significant differences between groups
Wagenaar 1990	7 B-C-B-C single case B N.D.T. (Bobath) C Brunströmm Acute (5-9 days)	IV	Total 20 weeks, 5 weeks each intervention phase 30 minutes/day	ARAT Barthel	No significant difference in arm function between treatments
Lord 1986	19 E Conventional 20 E Bobath Retrospective survey Within 8 months	V	For duration of rehabilitation	Telephone questionnaire about functional abilities	No meaningful differences
Patel 1998	85 E Impairment focused approach 99 E Disability focused approach Non-randomised comparison Acute (7 days) Barthel 4-10	III	Treatments occurred in 2 separate units, for duration of rehabilitation Impairment focused – repetitive remedial intervention Disability focused – aimed at restoration of normal function	Barthel Length of stay Discharge destination	No significant differences in disability and placement outcomes, but a 25% shorter length of stay for functionally oriented approach

E - Experimental group; MAS – Motor Assessment Scale; PNF – Proprioceptive neuromuscular facilitation; AROM – Active range of movement; N.D.T. – Neurodevelopmental treatment; ARAT – Action Research Arm Test

Table 4 Table of evidence of the comparisons of treatment combinations. Studies are listed in order of rating.

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OCCUPATIONAL THERAPY INTERVENTION FOR THE UPPER LIMB FOLLOWING STROKE (R10)

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1.0 INTRODUCTION

Stroke continues to be a major health concern around the world¹. The consequences of stroke are varied with impairments in both body structure and function often persisting. These impairments may limit the person's ability to perform various actions and tasks and participate fully in life situations². Environmental barriers may also limit participation. One consequence of stroke that is of interest to the International Society of Orthotists and Prosthetists (ISPO) is hemiplegia. While many health professionals are involved in the management of upper and lower limb impairments that are characteristic of hemiplegia, little is known about the effectiveness of the techniques used by health professionals to treat these impairments and the activity limitations they create. The purpose of this "Key Review of Practice" is to appraise the available scientific evidence on occupational therapy management of the upper limb following stroke and to discuss the findings against our personal knowledge of practice. To begin, a description of the scope of occupational therapy practice in the management of the people who have had stroke is provided. This is followed by a description of the methods used to conduct the review. The evidence is then presented in narrative style with the inclusion of supplemental tables. Finally, the findings of the review are discussed in light of contemporary practice and questions that arise are presented.

2.0 OCCUPATIONAL THERAPY

Occupational therapy for people who have had a stroke focuses on enhancing occupational performance skill and satisfaction. Occupational performance is the ability to perceive, recall, plan and/or carry-out needed or desired roles, routines, tasks and sub-tasks in order to achieve self-maintenance, play/leisure, school/productivity and/or rest objectives³. Occupational therapists provide occupation-focused therapy that usually includes instruction in methods of task performance, opportunities to practise performance in simulated and real-world contexts and the provision of equipment and adaptations to overcome the personal limitations or environmental obstacles that impede performance⁴⁻⁸. Occupational therapists recognize that the performance of tasks and routines is predicated on a person's biomechanical, sensory-motor, cognitive, intrapersonal and interpersonal component operations. Many occupational therapists, therefore, incorporate strategies and techniques that address dysfunction in these components within a broader occupation-focused framework. This may include counseling⁹, sensory-perceptual and cognitive re-training¹⁰, as well as, sensory-motor techniques (for example, the Bobath approach^{11, 12}, Proprioceptive Neuromuscular Facilitation (PNF)^{13, 14}, or Brunnstrom Movement Therapy¹⁵), techniques based on the application of motor control theory^{16, 17}, as well as, biofeedback¹⁸,

physical agents¹⁹ and orthotics²⁰. This broad view of occupational therapy as a profession that designs intervention to enhance occupational performance skill and satisfaction was used to structure the content of this review.

3.0 METHODS

A thorough and independent review of the available scientific literature was conducted. First, literature supplied by the National Centre for Training and Education in Prosthetics and Orthotics was reviewed. This included articles organized under the headings: Stroke *and* occupational therapy, stroke *and* shoulders, stroke *and* hand *or* wrists, stroke *and* spasticity/deformity and stroke *and* contractures. An additional search of literature published from 1980 to present was conducted using Web of Science indexing of all scientific journals published in English. Occupational therapy *and* stroke *and* upper limb were used as key words. Splinting *and* wrist *or* hand was added to the search as this is an intervention used by many occupational therapists and of primary interest to ISPO. Interventions that focus on participation, the environment, or the impact of sensory-perceptual, cognitive or psychosocial interventions in occupational therapy were deemed to be outside the scope of this review and, therefore, excluded. Supplemental searches were conducted through Science Direct, Journals@OVID and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) accessed through the University of Sydney library system. Finally, WebSPIRS and SCIRUS search engines were used to locate scientific information on the World Wide Web. The total number of articles obtained was 384.

A group of 52 final year occupational therapy students completing a hand therapy elective were each allocated articles to read. The objective at this stage was to identify those with occupational therapy content. Seventy-nine articles met this criterion. These 79 were read a second time and those authored by an occupational therapist or involved occupational therapists as part of the research team were identified. These criteria were applied in order to establish professional boundaries and to avoid excessive duplication with review papers on physiotherapy and the upper limb and on orthotic management of the upper limb. The 23 articles extracted through this process were read critically and independently by the two reviewers, summarized, and separated into one of the following two upper limb occupational performance goals for people who have had a stroke:

- 1) techniques that focus on enhancing the client's ability to use his/her arm and hand during occupational performance, and
- 2) techniques that focus on maintaining the potential for a client to use his/her arm and hand passively or actively during occupational performance.

Papers were then categorized within these goals by technique, rated according to type of study and level of evidence presented and then grouped into grades as described by Schekelle, et al²¹. Finally, bibliographic details were entered into Endnote® and tagged by keywords for easy retrieval and use in conducting this review.

4.0 EVIDENCE

Two systematic reviews of evidence about the effectiveness of upper limb interventions in occupational therapy were located^{22,23}. One of these included selected evidence generated in Physiotherapy²², the second included evidence of techniques used by occupational therapists to address impairments in cognition, perception, endurance and range of motion²³. Both of these reviews conclude that the evidence base for occupational therapy practice is equivocal. Relevant articles from each have been included below.

4.1 Occupational performance goal: Use the arm/hand during occupational performance.

This goal focuses on enhancing a person's ability to use his/her arm and hand as a dominant limb or as an active assist to reach for, stabilize, manipulate and/or hold tools, objects or environmental features during some or all daily routines and tasks when required. Evidence generated by occupational therapists about the effectiveness of interventions to achieve this goal fell into eight categories: occupation-enriched context, motor-learning methods, bilateral training, constraining the non-affected upper limb, traditional sensory-motor inhibition and facilitation techniques, physical agents and upper limb orthotics.

4.1.1 Occupation-enriched context

The use of meaningful contexts and real-world objects as the target of reach, grasp or release training has been investigated by many²⁴⁻²⁸. In an early study involving 50 subjects with a diagnosis of CVA²⁵, significant improvements in fine coordination (effect size .62) and muscle strength (effect size .33) resulted from therapy that included reaching for a slot machine (novel motor function therapy) combined with a traditional occupational therapy motor program (pulleys, pegboards, push boxes, suspension devices) in comparison to a program that consisted of the traditional occupational therapy motor program alone after a one-month trial. Unfortunately, this study lacked a no-treatment control group and the hours per week of therapy for each group were not specified. The effect of an occupation-enriched context on dimensions of upper limb movement constitutes a line of research conducted by others²⁶⁻²⁸. In the first of these²⁷, subjects with (n=14) and without (n=24) stroke were randomly assigned to one of two sequences: enriched context (participants reached forward for a food chopper and chopped a mushroom) and impoverished context (same chopper but disguised and no mushroom present) and vice versa. Positive effects of the enriched context on kinematic variables were observed in both groups but most significantly in those subjects with stroke. Mean effect size for outcomes for persons with stroke in this study was .44. In a second experiment²⁶ 13 subjects

with stroke were randomly assigned to one of six sequences that counterbalanced three contextual conditions for using a telephone: contextually complete (real working telephone); contextually incomplete (telephone receiver propped at an appropriate height); and, contextually impoverished (piece of wood similar to the handle of the phone receiver propped as in the second condition). Verbal instructions matched the conditions. No significant differences were found among the three conditions, and the effect sizes were negligible (.07). These findings were reversed in a later study by the same research team. In this study, people with (n=14) and without (n=24) stroke were randomly assigned to one of two sequences: object-present condition (reach for coins on a table) followed by object-absent condition or vice versa²⁸. The kinematics of the reaching movement revealed significantly more organized, preplanned movement by all participants when target objects were present. The average effect size of participants with stroke was large ($r=.63$). The effect of using functional mental imagery to create an occupation-enriched context was investigated by Page, Levine and Sisto²⁴ in a randomized controlled trial involving 16 chronic CVA patients. The experimental group (n=8) received occupational therapy consisting of NDT^{11,12} and compensatory strategies plus listened to a 20 minute tape recording that prompted imagery about using the arm for weight bearing or functional tasks. The control group (n=8) received the same occupational therapy treatment but listened to a 20-minute tape about stroke that prompted participatory attention. The upper extremity subtest scores on the Fugl-Meyer Motor Assessment²⁹ improved for both groups but significantly more in the experimental group (mean effect .72).

4.1.2 Motor learning methods

Research into the effectiveness of motor learning principles generated from within occupational therapy appears to be at the most basic level. Kilduski and Rice³⁰ studied the effects of qualitative and quantitative knowledge of results (KR) on the acquisition of a motor skill in 77 normal adults. Subjects were randomly assigned to one of four feedback conditions: quantitative, qualitative, quantitative and qualitative and no feedback (control group) provided during the acquisition phase of learning an isometric force production skill. Qualitative KR was in the form of verbal encouragement and quantitative KR was in the form of visual presentation of an algebraic number representing an error score. The main findings yielded a statistically significant difference between conditions containing qualitative verbal feedback about force accuracy and conditions containing visual quantitative feedback ($p<.05$). Although the subjects in this RCT were normal adults, the findings are relevant to providing feedback about upper limb performance to people recovering from stroke.

4.1.3 Bilateral training

The positive effect of bilateral simultaneous practise of reach tasks, known as bilateral isokinetic training (BIT), has been demonstrated in two well-controlled single system AB multiple baseline design studies³¹. Four subjects with hemi-

plegia from CVA participated over an eight-week period in each of the two studies. All subjects had most components of movement in the upper limb present but functional use of the limb varied. All were free from cognitive or perceptual impairments. In Study 1: videotapes were made of each subject attempting unilateral practice of a block placement activity, unilateral practice of simulated drinking and unilateral practice of a peg-targeting activity during a baseline phase (control condition). This was followed by practice of the same tasks but simultaneously using both hands (experimental condition). In Study 2: videotapes were made of each subject attempting the tasks with both hands interlocked during the baseline. This was followed by the bilateral, simultaneous method used in Study 1. Individually, the BIT intervention phases resulted in more accurate movements. Overall, methods used to manipulate phases for analysis and subsequent meta-analysis of the data demonstrated a strong, abrupt effect for the BIT phases for each of the three tasks ($p < 0.0005$ for each task).

4.1.4 *Constraining the non-affected limb*

Constraint-induced movement therapy (CIMT) is a method based on forced-use of limb principles³²⁻³⁶ combined with practise using the affected limb. Page, Sisto and Levine³⁵ studied the effectiveness of modified constraint-induced therapy carried out with an individual with chronic stroke, learned nonuse and a stable motor deficit in his dominant upper limb. The Fugl-Meyer Assessment of Motor Recovery²⁹ and Action Research Arm Test³⁷ were administered twice before intervention and the Motor Activity Log were administered once. The subject then participated in thirty-minute structured occupational therapy sessions three times per week for ten weeks. Twenty-four minutes of each session was spent in 'shaping', that is, using the affected limb in functional tasks (writing, opening containers, folding clothes, hanging coat) with some wrist and arm strengthening and compensatory training also included. Simultaneously, constraints consisting of a sling and a mesh polystyrene-filled mitt were applied to the left, non-affected arm and hand. Physical therapy concentrated on stretching, standing balance and gait training. After intervention, this subject showed a 9.5 point improvement on the Fugl-Meyer and a 13.5 point improvement on the ARA. These improvements remained stable three months post intervention. The Motor Activity Log also showed improvements in arm use. Although statistical data is not robust in a study of this design, the findings warrant attention. In another study³⁸, the perceptions and experiences of survivors of stroke with residual right hemiparesis who participated in a two-week CIMT home program were studied using a mixed-method design. The constraint for Case 1 consisted of wearing a sling on the left arm while attempting prescribed fine motor tasks with her right hand for six hours a day over a two-week period. Case 2 occasionally wore a glove on his left hand to remind him to use his right hand while he carried out prescribed fine motor tasks three hours per day over a two-week period. The Turning and Placing subtest of the Minnesota Rate of Manipulation (MRMT)³⁹ was used to measure change in

dexterity and the Arm Motor Ability Test (AMAT)⁴⁰ was used to quantify upper limb function in ADL performance. Quality of movement, ability to perform each component part in a compound task and time required to complete the task were measured. Qualitative findings were derived from semi-structured interviews that probed motivations for participating in CIMT and satisfaction with performance using the Canadian Occupational Performance Measure⁴¹ two weeks after completion of the program. The findings of this study are difficult to interpret although improvements in speed measured on the MRMT were supported by decreases in the time it took to complete items on the AMAT. Both subjects reported benefits as a result of the intensive nature of the program including the effect on their satisfaction when compared to inpatient rehabilitation they previously received.

4.1.5 *Traditional sensory-motor inhibition, facilitation techniques*

The effect of biofeedback versus Brunnstrom Movement Therapy⁴² on elbow range of motion in an RCT of subjects diagnosed as chronic CVA ($n=20$) was investigated in an early study⁴³. The control group received conventional occupational therapy consisting of Brunnstrom Movement Therapy for 30 minutes two times per week for four weeks. The experimental group engaged in exercises that included the use of instructional techniques to shape movement for 30 minutes two times per week. Audiovisual kinesthetic feedback was provided through an electrogoniometer. Measures taken of elbow range of motion at follow-up revealed significant improvements for both groups. Later, Trombly⁴⁴ used a counterbalanced, repeated-measures design to investigate the effect of resisted and ballistic exercises to improve the range of active finger extension in ten randomly assigned subjects with hemiplegia. Five different sequences of exercises were studied: 1) resisted grasp, 2) resisted extension, 3) grasp and release, 4) rapid, un-resisted extension and 5) slow un-resisted extension. Electrogoniometric measurements of finger extension during un-resisted opening of the hand were taken between each exercise. Results indicated that finger extension motion decreased substantially immediately after ballistic and resisted exercises and slightly after slow extension and flexion. The authors concluded that none of the techniques had an immediate effect on active finger extension but acknowledged that the small sample size may have obscured the effect. Unfortunately, the framework guiding the application of these techniques was not clear. Subsequent evidence generated from within occupational therapy about the effectiveness of various sensory-motor inhibition and facilitation techniques remains equivocal. One study in which an occupational therapist was part of the team applying the interventions does report evidence of the effectiveness of PNF⁴⁵ (See 4.1.6).

4.1.6 *Physical agents*

A cohort study of the effects of 1) EMG initiated electrical stimulation of wrist extensors (EMG-stim), 2) low-intensity electrical stimulation of wrist extensors combined with

voluntary contractions (B/B), 3) proprioceptive neuromuscular facilitation (PNF) exercises⁴⁵, or 4) no treatment in 22 right-handed chronic stroke patients was carried out over a one-year period⁴⁶. Subjects receiving EMG-stim were treated by an occupational therapist three times a week for a total of 36 one-hour sessions using an Automove stimulator. Transcutaneous electrical stimulation triggered by a low level of voluntary EMG activity in the target muscle was delivered to forearm wrist extensor muscles to produce joint movement. Stimulus intensity was set to produce maximum wrist extension, but not maximum force. In addition to wrist extensors, EMG-stim was used over paretic finger or elbow extensors, forearm pronators or supinators, or shoulder elevators or abductors according to the subjects' abilities as determined by the therapist. Subjects receiving B/B stimulation were trained to administer their own therapy using a Respond II electrical stimulator according to the investigators protocol for 30 minutes five times a week for three months. Low-intensity stimulation was applied to wrist extensor muscles. Stimulation was applied at an intensity that increased the subject's voluntary range of wrist extension without producing any visible movement at rest. A senior physiotherapist treated subjects receiving PNF for approximately one hour three times a week for a total of 36 sessions over a three-month period. PNF treatments encompassed the whole upper limb, including wrist extension. The Fugl-Meyer Assessment of Motor Recovery, grip strength measured through use of the Jaymar hand dynamometer, finger tapping as described by Reitan⁴⁷ and three items on the Jebsen-Taylor⁴⁸ hand function test (card turning, simulated feeding, small objects) were used as pre-test and post-test measures. Measurements were also taken at three months and nine months after treatment. Improvements were seen on all measures on items subjects were able to complete. Fugl-Meyer scores following PNF improved 18%, B/B improved 25% and EMG-stim improved 42% and these gains were maintained at follow-up. No improvements were seen in the control group. The authors conclude that chronic stroke patients can achieve and maintain improvements in the upper extremity, especially with treatments combining electrical stimulation techniques with voluntary effort.

Chae, Bethoux, Bohine, Dobos, Davis and Friedl⁴⁹ investigated the effects of surface neuromuscular stimulation on upper limb motor and functional recovery in acute hemiplegia in an RCT involving 46 stroke patients. Subjects in the experimental group received surface neuromuscular stimulation over the paretic arm on the extensor digitorum communis and the extensor carpi radialis brevis and longus administered by an occupational therapist and the control group received placebo stimulation in a matched pattern. All subjects received daily one-hour sessions over fifteen days. Measures were taken of upper limb motor recovery using the Fugl-Meyer Motor Assessment. Functional recovery was measured using the self care component of the Functional Independence Measure (FIM). The results of this study yielded significant gains in Fugl-Meyer scores for the treatment group immediately after treatment and at four week and twelve week follow-up. The sample was

too small to detect differences in self-care function. The authors concluded that neuromuscular stimulation enhances upper limb motor recovery in patients with acute stroke and that the affect is maintained for up to three months after completion of treatment. Later, the immediate effects of neuromuscular electrical stimulation (NMES) of the wrist flexors in combination with maintained passive stretch on decreasing muscle tone in those spastic wrist flexor muscles following a single ten-minute treatment session in a sample of 21 people with stroke was studied in another pre-test, post-test design⁵⁰. Effects were measured using a torque meter⁵¹. Limitations in the instrumentation used in this study existed, however, an independent *t* test showed a mean decrease in resistance for subjects receiving NMES to the flexor group and this was significantly greater than that for subjects receiving maintained passive stretch only ($p < .001$).

4.1.7 Upper limb orthotics

Although occupational therapy authors have recommended the use of upper limb orthotic systems to enhance the functional use of the hand in people who have had a stroke²⁰,⁵², little research evidence to support this was found. The effects of inflatable pressure air splints on upper limb function was studied in 18 subjects with hemiplegia⁵³. Matched pairs of subjects were randomly assigned to a splint or no splint condition. The treatment group wore an air splint on the hemiplegic arm for five days a week over a three week period. The control group did not wear the splint. Fugl-Meyer Assessment of Motor Recovery scores pre- and post-test revealed no change in motor function. Post-test measures, however, were not taken until 24 hours after the splint was removed for the final time and the weekend removal of the splint may further have influenced the results. These authors continued to recommend this form of intervention as an adjunct during regular therapy sessions in a subsequent publication⁵⁴.

Although not specific to hemiplegia, the work of Chan and Chapparo⁵⁵ has relevance to this review. These researchers investigated the effect of wrist immobilization on upper limb task performance in nine normal male subjects between the ages of 60-79. The Motion Analysis ExpertvisionTM system was used to track and analyze changes in time and range of upper limb movement during splinted and non-splinted phases while subjects performed items on the Jebsen Hand Function Test⁴⁸. An analysis of these parameters revealed statistically significant increases in the time taken and the total degree of shoulder motion used. The analysis also showed significant decreases in the total elbow motion used during the wrist-immobilized condition. These findings have implications for the use of wrist-hand orthoses to improve hand use in clients whose shoulder and elbow control is impaired.

4.2 Occupational performance goal:

Maintain potential for use of the arm and hand during occupational performance.

Occupational therapists use techniques to prevent secondary problems in the upper limb, such as pain, oedema, soft-

tissue injury and contracture. The prevention of secondary problems maintains the potential for the arm and hand to be used passively or actively in daily tasks. In many cases this is to ensure the affected arm and hand does not, in fact, interfere with task performance (eg. placing the hand in a shirt sleeve). Techniques to achieve this goal investigated by occupational therapists include: oedema management, slings/positional supports and upper limb orthotics.

4.2.1 Oedema management

Although a variety of techniques are used in occupational therapy to control oedema, little research evidence exists. In one study an ABA single system design was used to evaluate the effect of continuous passive motion on oedema in the hands of two people with left-sided hemiplegia one month post stroke⁵⁶. Baseline measures of oedema were taken daily using a Volumeter and the sizing of jeweler's rings positioned at the base of one finger over the five-day baseline period. Intervention consisted of daily CPM administered via the Toronto Mobilimb H2 Hand set at a 45° angle over a subsequent five-day period. Repeat measures of oedema followed intervention during the treatment phase. Follow-up measures were taken again over the five days of the second A phase. Visual analysis of plotted data for the baseline-treatment-baseline phases indicates that the CPM device had an immediate effect on reducing oedema in these two subjects.

4.2.2 Slings / UL positional supports

Occupational therapists prescribe and provide sling supports and other positional devices to support and protect a weakened shoulder following stroke⁵⁷⁻⁵⁹. Little evidence of effectiveness exists. Spaulding⁶⁰ conducted a static biomechanical analysis of the effect of four different shoulder support systems (two over-arm sling configurations, a Bobath axial role, and a lapboard, arm trough or half trough support system) using a calculation of body mass and gravitational force. The results indicate that slings with straps over the unaffected shoulder provide continuous support for the flaccid limb; the Bobath axillary roll may introduce an unwanted lateral force. Lapboards must be maintained at an appropriate distance from the subluxed shoulder to be effective.

4.2.3 Upper limb orthotics

Physicians first described orthotic intervention for the wrist and hand in clients with spastic hemiplegia from stroke in the 1960^{61, 62}. In occupational therapy, splinting a spastic hand for the purpose of controlling tone appeared in the literature in 1959⁶³. Subsequently, numerous orthotic designs and practice guidelines have been described^{20, 64}, research has been carried out⁶⁵⁻⁷⁰ and one systematic review of some of this evidence produced²³. Research findings, however, are inconclusive and occupational therapy orthotic intervention with clients who have had a stroke remains controversial^{23, 71, 72}.

Mathiowetz, Bolding and Trombly⁶⁸ tested the effects of three hand splints (volar resting splint, finger spreader splint, firm cone) versus no splint on eight healthy subjects

and four subjects who had moderate to severe spasticity of the wrist, fingers or both following stroke. Electrical activity (proxy for spasticity) in the wrist or finger flexor muscles was measured following exercises involving the affected wrist/hand. No significant differences were found between any groups but flaws in the design of the study preclude any generalization of these findings. Others⁷⁰ compared the immediate effects of dorsal, volar and no splints in reducing hypertonicity in the wrist flexors of spastic hemiplegic subjects in this RCT involving 30 subjects. Measures included (1) passive range of motion (PROM), (2) angle of point of stretch reflex, (3) resistance to passive wrist extension and (4) force of spontaneous wrist flexion. A significant reduction in hypertonicity following both dorsal and volar splint application on passive range of motion and resistance to passive extension measures ($p < .05$) and a significant reduction in hypertonicity as measured by spontaneous flexion following two hours of dorsal splint wearing ($p < .05$) were found. No significant reductions in hypertonicity were noted on the angle of point of stretch reflex measure or on the force of spontaneous flexion measure. The effects of a 'resting hand splint' on dimensions of passive range of motion, oedema, upper limb function, hand function, muscle tone and cosmetic appearance has also been investigated in a subject with flaccid hemiplegia over an eight-week period in comparison to a matched sample who was not splinted⁶⁵. Although the sample size was small, it is worth noting that no negative changes on any variable were measured in the splinted subject while the unsplinted subject developed measurable oedema around the metacarpal-phalangeal joints of the affected hand. The effect of wearing regime has also been studied. Langlois, Pederson and MacKinnon⁶⁷ studied the effect of three different wearing regimes for a Snook type finger spreader splint⁷³. Nine participants with hemiplegia resulting from stroke were randomly assigned to one of three wearing-regime conditions for four weeks. The results of this study was that the longer wearing schedule had the biggest effect on reducing spasticity; however, these statistics have subsequently been refuted²³. Recently, a pivotal randomized, assessor-blinded trial evaluating the effects of four weeks of hand splinting on the length of finger and wrist flexor muscles, hand function and pain in people with acquired brain impairment has been conducted⁷⁴. Twenty-eight adults with either stroke or brain injury of not more than six months duration were recruited. All were unable to actively extend the wrist. Subjects were randomly allocated to control and experimental groups after baseline measurements were taken of the following: wrist and finger flexor muscles using a torque-controlled measurement⁷⁵, upper limb function on components of the Motor Assessment Scale (MAS)⁷⁶ and upper limb pain as indicated on a vertical Visual Analogue Scale (VAS)⁷⁷. Subjects in both groups participated in routine therapy for individual motor training and upper limb stretches reportedly aligned with the Motor Relearning Program for stroke^{78, 79} five days a week for the four-week period of the study. Upper limb motor training consisted of an individually designed motor training program aimed at improving performance in upper

limb tasks. Stretching consisted of two 30-minute low-load stretches applied to the upper limb five days a week for the duration of the study and for a follow-up period. This included (1) a seated weight-bearing stretch of the upper limb in the classic NDT reflex inhibiting position (shoulder external rotation, abduction, slight extension, elbow extension, forearm supination, wrist and finger extension); and (2) a seated stretch of the upper limb using an inflatable air splint with the upper limb approximating the same position as in (1) with the exception of the thumb which was abducted and the fingers which were free. Subjects in the experimental group also wore a static, palmar resting mitt-splint on a nightly basis for a maximum of 12 hours each night for the duration of the study.

The major finding of this RCT was that subjects with acquired brain impairment who were participating in routine motor training and upper limb stretches did not show detectable or important changes in wrist and finger flexor extensibility after wearing a splint nightly for four weeks. Subjects in the control group did not lose wrist and finger flexor extensibility in this four-week period. Second, there was no evidence of clinically significant effects of splinting on upper limb function as measured by component or summed scores of the MAS. Changes in pain scores were not significant. These authors concluded that four weeks hand splinting in the functional resting position does not improve contracture, hand function or pain in adults with acquired brain impairment who are already participating in routine motor training and upper limb stretches. A more accurate conclusion is that four weeks of nighttime hand splinting in the 'mitt' resting position was no more beneficial than the established therapy regime

5.0 EVIDENCE STATEMENT

The evidence reviewed above is not strong but does provide preliminary guidance for practice and research (refer to Table 1). Caution is advised in interpreting these statements outside the context of this paper.

- Practice that involves the use of everyday items and functionally relevant contexts results in better motor control of the upper limb. (Grade B)
- Practice that involves the use of both arms simultaneously results in better control. (Grade B)
- Practice that involves constraining the non-involved limb influences outcomes in motor control of the affected limb. (Grade C)
- The use of electrical stimulation in conjunction with practice using the upper limb improves voluntary motor control in the upper limb. (Grade B)
- Qualitative, verbal feedback about motor performance results in better performance than visual, numerical information. (Grade A)
- Application of a wrist-hand orthosis to a non-hemiplegic upper limb places more demand on the shoulder and elbow motion required to complete functional upper limb tasks. (Grade B)
- A resting wrist-hand orthosis applied to a flaccid hand does not cause contracture and may prevent oedema. (Grade IV)

- There is no difference in effect some variables between the application of a volar or palmar orthosis. (Grade B)
- The application of an orthosis is better than nothing or low-intensive therapy. (Grade B)
- Intensive therapy that incorporates stretching is as effective as night positioning in a mitt-type resting wrist-hand orthosis. (Grade A)
- Slings that distribute weight over the unaffected side provide the best support for a flaccid upper limb. (Grade *)
- Continuous passive motion may be effective in reducing oedema (Grade C)

6.0 DISCUSSION

The findings of this review support the assertion that occupational therapists use a variety of techniques to improve upper limb occupational performance in people with hemiplegia from stroke. Occupational therapists have generated little conclusive evidence about the effectiveness of any technique used to treat upper limb impairment following stroke. The lack of evidence should not be interpreted to mean that occupational therapy practice is unsound; rather, more research is needed.

One problem plaguing effectiveness studies is theoretical. This is especially true of research into techniques where a sensory-motor or motor learning rationale is provided. Several

authors have noted that upper limb treatment techniques used by the therapists are not easily differentiated^{22, 58, 80}. What one therapist labels motor relearning, another therapist will describe as neurodevelopmental therapy. This is apparent in the study by Lannin, et. al.⁷⁴ reported earlier. Similar disparities can be identified elsewhere^{31,44}. This has direct implications for future practice and research in occupational therapy and physiotherapy in this area. A theoretical model capable of integrating various theoretical perspectives on what effective upper limb occupational performance entails is needed. Such a model would assist therapists in making choices about techniques to be used, articulating a rationale for choices made and identifying outcomes expected. This, in turn, would aid in the formulation of specific research questions, the development of quantitative and qualitative research designs to answer these questions and the design and selection of measures that are sensitive to treatment effect.

The strongest evidence generated within occupational therapy supports the use of an occupation-enriched context. While some of the research conducted into the effectiveness of other techniques used everyday tasks as targets of reach, grasp or release, many studies did not. No study reviewed makes reference to the influence of hand dominance on the choice of target object or intervention method used. It is accepted that a difference exists in how people use the dominant versus the non-dominant hand. Is hand dominance an important consideration in selection of technique and intervention approach? Is there a variation in the type and pattern of muscle recruitment present between these two hands? If so, future research needs to take this into consideration.

Splinting the wrist and hand in a person with hemiplegia has traditionally been done to 'inhibit spasticity' or 'prevent contracture'. The functional resting splint seems to be the splint of choice among therapists who do splint. Studies investigating the effectiveness of splinting in hemiplegia have applied the same splint to all subjects in the experimental group. On close examination of the hemiplegic hand, however, it is apparent that there is wide variation in the type and pattern of muscle imbalance present. This is obvious both between people at different levels of recovery and also among people who are at the same stage of recovery. Is a standard resting splint suitable for all persons with hemiplegia? What criteria should factor in to orthotic design for people with hemiplegia from stroke? This needs further exploration and consideration in future research.

Many occupational therapists prescribe slings to protect the shoulder from secondary trauma. This is typically expressed in terms of reducing subluxation and preventing pain. Those who do not prescribe slings cite prevention of learned helplessness, contracture and difficulty with donning/doffing as reasons. Little reference is made to

the effect of a sling on oedema management or postural symmetry during standing and walking. As with sensory-motor techniques, motor learning approaches and orthotic intervention, theoretical confusion seems to also plague practice in this area. Questions that arise include: What criteria should factor in to shoulder sling design for people with hemiplegia from stroke? What purposes do slings serve? This, too, requires further exploration and investigation.

In summary, the body of knowledge about the management of hemiplegia following stroke in people is not strong. This is especially true of that generated from within occupational therapy. It is hoped that this, "Key Review" and questions that have been raised will contribute to shaping the development of both therapy and orthotic services for people following stroke.

EVIDENCE TABLE: Use the arm/hand during occupational performance

Study	Evidence Rating	Design & Subjects	Intervention & Dosage	Outcome Measure	Results
4.1.1 Occupation-Enriched Context:					
Smedley, Fiorino, Soucar, Reynolds, Smedley, & Aronica (1986)	IIb	n=50 stroke	C = pulleys, pegboards, push boxes, suspension slings E = + reach for slot machine ? hrs per week over 4 weeks	Beck Depression Inventory; PULSES Profile; Judgments of ROM, Strength, Gross Coord, Fine Coord	Significant improvements in fine coordination and muscle strength when context is occupation-enriched
Wu, Trombly, Lin, & Tickle-Degnen (1998)	IIb	n=14 chronic stroke n=24 healthy case control	Condition 1: Reach to food chopper & chop mushroom Condition 2: Reach to disguised food chopper & push handle down 10 trials/condition/1 day	Kinematic analysis	Better organization of reaching when context is occupation-enriched
Trombly, & Wu (1999)	IIb	n=14 chronic	Condition 1: Reach to pick up favorite snack Condition 2: Reach forward 10 trials/condition/1 day	Kinematic analysis	Better organization of reaching when context is occupation-enriched
Wu, Trombly, Lin, & Tickle-Degnen (2000)	IIb	n=14 chronic	Condition 1: Reach to scoop coins off table Condition 2: Reach forward 10 trials/condition/1 day	Kinematic analysis	Better organization of reaching when context is occupation-enriched
Page, Levine & Sisto (2001)	IIb	n=16 chronic stroke	C = NDT, compensation + 20 min tape about stroke E = NDT, compensation + 20 min audiotape prompting imagery about functional use in weight bearing and reach	Fugl-Meyer Motor Assessment	Improved motor control in both groups but significantly more in experimental group
Grade: B					
4.1.2 Motor Learning Methods					
Kildusky, & Rice (2003)	IIa	n=77 healthy adults RCT	Feedback (KR) provided during isometric force production skill Group 1 - Quant. KR = error score; Group 2 - Qual. KR = verbal praise; Group 3 - Combined = both Group 4 - Control - no feedback	Computer detection of force and accuracy of taps	Significant improvements in force accuracy during qualitative KR conditions
Grade: A* (sample = healthy adults)					
4.1.3 Bilateral Training					
Mudie, & Matyas, (2000)	IV	n=12 cva single cases (multiple baseline) n=4 each series	E: Bilateral Isokinetic Training (BIT): identical movements performed by both upper limbs. C: Study 1: Unilateral performance of 3 tasks C: Study 2: Concurrent performance of different tasks by each arm C: Study 3: a) = same as Study 1; b) = bilateral performance done with hands linked (NDT) 10 practice trials/session; 30-40 sessions over 6-8 weeks	Valid and reliable observational kinematic scales subjected to semi-statistical analysis	Significant abrupt effect for BIT phases across all studies
Grade: B					
4.1.4 Constraining the non-affected limb					
Page, Sisto & Levine (2002)	VI	n=1 chronic stroke	Sling and mitt applied to non-affected limb; 'shaping' use of affected limb 30min/.3 times per week/ 10 weeks.	Fugl-Meyer; Action Research Arm Test; Motor Activity Log	Improvements on all measures; maintained at 3 mo re-test
Gillot, Holder-Walls, Kurtz, & Varley (2003)	VI	n=2 cases	Case 1: sling on L arm; fine mtr task training RUL 6hrs/day for 2 wks Case 2: glove on left had; fine mtr training 3hrs/day for 2 wks	Minnesota Rate of Manip. Turning & Placing Sub-Test; Arm Mobility Test; Semi-structured interview; Can.OP Meas.	Improvements in speed on MRM; Decrease in time on AMAT; Client-perceived benefits
Grade: C* (small samples)					

4.1.5 Traditional sensory-motor inhibition, facilitation techniques

Greenberg, & Fowler (1980)	IIb	n=20 chronic CVA	C = Conventional OT (Brunnstrom) E = Exercises with AV kinesthetic feedback through electrogoniometer	ROM	Improved for both groups
Trombly, & Quintana (1983)	IIb	n=10 chronic CVA cohort counterbalanced, repeated measures	Condition 1: resisted grasp Condition 2: resisted finger extension; Condition 3: grasp & release; Condition 4: rapid, unresisted finger extension; Condition 5: slow, unresisted finger extension Three repetitions, 2 min. rest between; all over 1 day (? PNF Treatment framework)	AROM of finger extension, EMG activity	Finger extension decreased immediately after ballistic and resisted exercises and slightly after slow extension and flexion

Grade: inconclusive

4.1.6 Physial Agents

Chae, Bethoux, Bohine, Dobos, Davis, Friedl (1998)	IIa	n=46 stroke RCT	C: routine therapy E: Surface neuromuscular stim. Administered by OT on antagonist wrist/finger extension; 1 hr p/day for 15 days	Fugl-Meyer, FIM	Significant gains in Fugl-Meyer scores immediately after treatment & at 4 and 12 weeks follow-up.
King (1996)	IIb	n= 21 chronic stroke	Condition 1: passive stretch of wrist flexors Condition 2: Neuromuscular elect stim on agonists (spastic wrist flexors). 1 x 10 min session	Torque meter	Mean decrease in resistance of wrist flexors following NMES
Kraft, Fitts, & Hammond (1992)	III	22 chronic stroke, cohort study	Gp 1: EMG stim of wrist extensors 3xp week for total 36 one-hour sessions in OT Gp 2: Low-intense elect. stim c/w voluntary act self-administered – wrist extensors 30 min, 5x p week for 3 mo. Gp 3: PNF emphasizing whole arm and wrist extension in physio 3x p week for 36 one-hr Gp 4: No treatment	Fugl-Meyer Grip strength Halstead-Reitan finger tapping Jebsen-Taylor Hand Function Test	Improvements seen on all measures – Fugl-Meyer following PNF up 18%, following low-intens stim up 25%, following EMG-stim up 42%. Gains maintained at 3 and 9 months follow-up

Grade: B

4.1.7 Upper Limb Orthotics

Poole, & Whitney, Hangeland, & Baker (1990)	IIb	n=18 stroke matched pairs randomly assigned to condition	C = conventional therapy E - Inflatable pressure air splint worn for five days a week over 3 weeks.	Fugl-Meyer	No difference however measures not taken until 24 hrs after splint removed for final time.
Chan & Chapparo (1999)	IIb	N=9 healthy men	Condition 1: no splint Condition 2: wrist-hand orthosis: long opponens type Performance of items on the Jebsen-Taylor Hand Function Test	Kinematic analysis of performance	Increases in shoulder and elbow motion used and time taken to complete test times during splinted condition

Grade: Inconclusive *

(C = control, E = experimental)

EVIDENCE TABLE: Maintain potential for use of the arm and hand during occupational performance

Study	Evidence Rating	Design & Subjects	Intervention & Dosage	Outcome Measure	Results
4.2.1 Oedema management					
Dirette, & Hinojosa, (1993)	VI	n=2 one month post stroke ABA	Daily Continuous Passive Motion over 5 days	Volumeter and measurements of finger circumference using Jeweler's rings	CPM had an immediate effect on reducing oedema
Grade: C					
4.2.2 Slings / UL positional supports					
Spaulding, (1999)	VII	Hypothetical person	Biomechanical analysis of shoulder support provided by four supports: Overarm slings x 2, Bobath axillary roll, laptray	2 dimensional model for force/mass calculations	Overarm slings support shoulder better than Bobath axillary roll or laptray
Grade: *					
4.2.3 Upper limb orthotics					
Lannin, Horsley, Herbert, McCluskey, & Cusick (2003)	IIa	n=28 acquired brain impairment >6 mo onset	C: Individually designed upper limb motor training 5 days p/week for 4 weeks; Two x 30 min. stretches of the upper limb (self-imposed & air splint); 5 days p/week; 4 weeks. E: Above + static, palmar resting mitt-splint; 12 hrs, nightly, 4 weeks	Motor Assessment Scale Torque measure of tendon extensibility Pain Scale	No change in wrist or finger flexor extensibility after night wearing of mitt-resting splint. Control group did not lose wrist and finger flexor extensibility
Langlois, Pederson & MacKinnon (1991)	IIb	N=9 chronic CVA	Finger spreader splint to decrease spasticity Group 1: worn 6 hrs /day; Group 2: worn 12 hrs / day; Group 3: worn 22 hrs/ day Over 4 week period	Angle of resistance	Longer wearing regime had biggest effect but statistical flaws exist
Rose, & Shah (1987)	IIb	n=30	Condition 1: Volar splint Condition 2: Dorsal splint Control: no splint 2 hrs	PROM, Angle of point of stretch reflex; resistance to passive wrist extension; force of spontaneous flexion	Significant reduction in hypertonicity following dorsal and volar splint application on PROM and resistance to passive extension and reduction in force of spontaneous flexion.
Mathiowetz, Bolding & Trombley (1983)	IV	n=12 (8 healthy, 4 chronic stroke)	Condition 1: Volar resting splint Condition 2: Finger spreader splint Condition 3: Firm cone (orthokinetic splint) Condition 4: no splint Exercises involving the affected wrist/hand	Electrical activity as proxy for spasticity after exercises involving the affected wrist/hand on splint removal	No differences between conditions for either group
Bowen, & Germanos (1988)	IV	n=2 CVA (flaccid hemiplegia)	C: regular therapy E: Resting hand splint; 8 weeks, (? hrs per day)	PROM, oedema, upper limb function, hand function muscle tone and cosmetic appearance	No changes on any variable following splint. Subject in non-splinted condition developed oedema around MP joints of affected hand

(C = control, E = experimental)

Grade: inconclusive

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PHARMACOLOGY AND UPPER LIMB POST STROKE SPASTICITY; A REVIEW (R11)

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Post stroke upper limb spasticity is rarely useful. At best it is acceptable when it is not disabling, however there are various ways in which spasticity can be disabling. Before treatment, the real difficulty is to define, as precisely as possible, for each patient, how spasticity is disabling, i.e. the place of spasticity among other neurological disturbances including motor impairment, sensory loss, orthopaedic limitation, abnormal movement and even neuropsychological disorders.

Studies conducted among post stroke patients are few. Knowledge is largely derived from studies of children with cerebral palsy, and adults with spinal cord injury, multiple sclerosis or brain injury. The present review will deal with the pharmacological, general or local treatments, available for post stroke upper limb spasticity. The studies included are either completely or partly devoted to stroke. The review is based on Medline research, assisted by the National Centre for Training and Education in Prosthetics and Orthotics (Glasgow), and the analysis of the references in each paper considered. Each paper was rated according to the level of evidence table recommended by the organising committee. Grade of recommendation for groups of papers were assigned according to Shekelle et al [1].

GENERAL PHARMACOLOGICAL TREATMENTS (3 reviews, 4 randomised double blind studies, 2 open studies and 1 expert opinion)

Five drugs have been proved to be effective in post stroke spasticity: Baclofen, Dantrolene, Tizanidine, Diazepam and Chlorazepate dipotassium [2]. The latter drug seems to be rarely used, and has not been the subject of a sufficient number of publications to be discussed. Diazepam is also not commonly used, because its effects seem less striking in post stroke spasticity than in multiple sclerosis or spinal spasticity, or at least, more often overshadowed by adverse effects [2]. Clonazepam can be used [3], but has also not shown real evidence of benefit for stroke patients.

Most of the studies concerning Baclofen involved patients with multiple sclerosis or spinal pathologies. When reviewing this drug, Gracies et al only found one double blind study and 3 open studies of stroke patients, who seemed to benefit less than other patients from baclofen with more significant side effects [2]. No further reports have appeared since these publications.

Dantrolene Sodium

Most of the studies concerning Dantrolene Sodium were published between 1971 and 1976, demonstrating its capacity to reduce spasticity. According to the review by Pinder et al [4], 3 open trials had included hemiplegic patients and patients with spinal cord injuries. The results of one trial seemed better for spinal cord spasticity, but those of the two others showed no difference. Since that review, two relevant studies have been published. Ketel and Kolb

[5] reported a significant improvement in upper extremity strength with a reduction in passive stretch, in 15 patients followed for 15 months, and treated with 50 to 400 mg/day. Katrak et al [6] who followed 38 early (within 8 weeks) post stroke hemiplegic patients, in a double blind placebo controlled crossover study over 14 weeks, did not find the same efficacy with 200 mg/day. Spasticity of the elbow and knee flexors/extensors did not change, and neither did motor function and the Barthel index.

Tizanidine

Wagstaff and Bryson reported in their review that the antispastic efficacy of Tizanidine had been demonstrated in several placebo - controlled trials, with wide inter patient variations as regards the effective and tolerated doses (2 to 36 mg/day). None of these trials involved post stroke patients. The efficacy of Tizanidine seemed similar to that of Baclofen and Diazepam, but its global tolerability was markedly better [7]. The only one double blind trial, carried out in hemiplegic patients with chronic spasticity, compared the efficacy and tolerability of tizanidine with that of diazepam. Spasticity was reduced without significant difference between groups, but walking distance improved significantly more with tizanidine; upper limb function was not assessed [8]. In an open trial, thirty patients with post stroke hemiparesis who were treated with 12 to 24 mg/day, exhibited a significant decrease in spasticity on Ashworth's scale with a slight improvement of the possibility of self-serving and walking [9]. Nevertheless, very little information was given about the means of assessment.

Since the review by Wagstaff, 2 well-conducted studies have been published. Gelber et al [10] studied 47 patients during a multicentre open label 16-weeks trial. Special attention was paid to the upper limbs as regards the spasticity of elbow and wrist flexors/extensors, motor strength, grip, upper limb function, and the Barthel scale. A decrease in spasticity was observed, with a linear dose-response relationship up to week 16 associated with a decrease of pain, but there was no improvement in functional activities. However only 32 patients completed this study, as 13 dropped out due to adverse events. Lastly, in a randomised, double blind placebo-controlled study with a cross over design, Meythaler et al [11] reported similar results for 17 patients including 9 with stroke, who were given an average dose of 25 mg during the 6-weeks treatment period.

Summary and recommendations: the studies reviewed were at level of evidence I [2-4,7], IIa [5,6,8,11] or VI [9,10]. Baclofen, Dantrolene and Tizanidine have been proved to reduce spasticity in Multiple sclerosis, but concerning upper limb post stroke spasticity: efficacy of Baclofen is not demonstrated, efficacy of Tizanidine has been observed in open studies but without attention to upper limb function, and efficacy of Dantrolene sodium

is questionable, positive results being observed in some open studies but not in the only double blind placebo control study. Tizanidine is the best tolerated of these drugs. In our experience, this apparent efficacy of oral drugs is questionable. Severely spastic patients sometimes feel an improvement but show no evidence of it. The best effect of oral drugs seems to be on moderate spasticity, but when the treatment is stopped after a long period, no further change is observed in most cases.

Grade of recommendation: B

INTRATHECAL BACLOFEN

Intrathecal baclofen (ITB) with implantable pump was initially used to reduce spasms and spasticity in non-ambulatory subjects with spinal cord injuries or multiple sclerosis, and later for cerebral palsy and traumatic brain injuries [12]. Its efficacy in stroke patients was only recognized recently, perhaps owing to concerns about weakening the unaffected limbs [13]. In his review, O'Brien did not find any controlled study of ITB in post stroke patients [14]. Although the main targets of ITB are the lower limbs and trunk, the improvement of upper limb motricity also contributes to functional improvement: in a meta analysis of 17 studies, Sampson et al [15] noted that 72% of the patients improved their mobility in a wheelchair, and that 96% of the patients concerned improved their ability for transfers.

The only publication regarding ITB concerned with stroke is the randomized double blind placebo-controlled study by Meythaler et al [16]. This study of 17 patients followed up for 12 months is especially interesting, because attention have been paid to upper limbs. A significant reduction in the Ashworth and spasms scores was observed, although it was slightly smaller than for the lower limbs. The result lasted for one year without any weakness of the unaffected upper limb. Upper limb motricity and functional abilities were not assessed, but the authors specified that all dependent patients were more comfortable and easier to manage at home. Unfortunately the functional and motor initial status of the patients were not specified.

Summary and recommendations: the studies reviewed were at level of evidence I [12-15] or IIa [16]. Few studies provide information about upper limb spasticity but, as claimed by G.Francisco [17], ITB deserves to be considered for stroke patients, especially those with very severe hypertonia. Adverse events such as infection, pump failure, catheter migration, seizure, can be controlled, and the cost of ITB have to be compared with the benefit and the cost of the nursing of severe spastic hemiplegic patients [15]. Further studies are needed to assess the place of ITB after stroke, in order to confirm the functional benefit for stroke survivors with severe spasticity and to assess the benefit of ITB in less severe hemiplegia (but probably for the lower rather than for the upper limbs).

Grade of recommendation: B

LOCAL TREATMENT BY CHEMICAL NEUROLYSIS WITH ALCOHOL OR PHENOL

Local treatment by chemical neurolysis to reduce spasticity was suggested many years ago [see ref. in 18]. It was mainly developed between 1950 and 1970 for children with cerebral palsy [19] and para or tetraplegic patients with spinal cord injury, and later for multiple sclerosis or hemiplegia [20]. Many articles or chapters of books describe the use and techniques of these chemical neurolysis but do not provide much evidence in its favour, and only small series were reported. We did not find any study evaluating chemical neurolysis versus other local treatments such as botulinum toxin.

Alcohol or phenol induces neurolysis by demyelinating the nerve. Phenol is used in a 5 or 6.7 % aqueous dilution, or a glycerine dilution for intraneural injection. Alcohol is at present used in a 50 or 60 % saline dilution. Neurolysis can be induced by intramuscular injection at the motor point (s) or by direct nerve neurolysis, by either percutaneous or open intraneural injection. This last technique has been described for nerves which contain both sensory and motor components, to prevent post-block dysesthesia and loss of sensation [21], but does not seem to be widely used. The techniques used today are the same as those for locoregional anaesthesia, with a needle that is coated with polytetrafluoroethylene except for the tip, and is connected to a neurostimulator.

1. Pectoralis major muscle:

Pelissier et al reported 13 cases of pectoralis major spasticity, treated with 60 % diluted alcohol, injected at two motor points [22]. A marked reduction of tone appeared in 10 of the 13 patients, and lasted for 60 days and 120 days for only 4 of them (Table 1). These authors mentioned the positive impact of this treatment on algoneurodystrophia.

2. Subscapularis muscle:

Hecht reported 13 hemiparetic patients with spastic painful shoulder, treated by intramuscular injection at two motor points of 6.7 % aqueous phenol solution [23]. An immediate significant improvement of passive range of motion (PROM) was observed, especially for external rotation (Table 1). Pain was not systematically evaluated but appeared to decrease. No systematic follow up was conducted.

3. Musculocutaneous nerve:

3.1. Kong and Chua reported the use of the percutaneous musculocutaneous nerve block using a 50 % dilution of alcohol in water, in 20 post stroke patients [24]. The significant reduction of spasticity observed (Table 1), lasted for 6 months and a positive effect on walking balance was noted in 7 of the 14 ambulatory subjects. Four of the 5 patients with pain reported its relief. Using the phenol, Keenan et al suggested enhancing the improvement in some patients by concomitant phenol motor point block of the brachioradialis muscle [25].

3.2 Garland et al described the use of the musculocutaneous nerve block with a surgical open technique in 12 patients (1 stroke, 11 brain injury) using 3 % phenol in glycerin injected into the nerve [21]. Evaluation, which was hardly described, was based on PROM, with a follow up ranging from 1 to 60 months. A mean gain of extension of 43° was

observed in 8 patients, with an improvement in self-care ability. The effects seemed to subside within 6 months.

4. Median Nerve:

Pelissier et al treated 6 patients by percutaneous alcohol neurolysis of the median nerve at the elbow bend (Table 1) [22]. Evaluation was only based on the modified Ashworth scale (MAS) of the wrist and finger flexors. The immediate decrease in spasticity observed lasted for 2 months for 4 patients and 4 months for 2.

5. Wrist and finger flexors muscles:

Kong et al treated 30 patients with a functionally useless hand due to wrist and fingers spasticity, by percutaneous intramuscular injections of 50 % alcohol (Table 1) [26]. A significant reduction in spasticity and an improvement in the PROM of the proximal interphalangeal joints of the 4 last fingers were noted and lasted for 6 months.

6. Ulnar nerve: (no study of stroke patients)

In a retrospective review, Keenan et al reported 21 patients who had phenol neurolysis of the ulnar nerve by the surgical open technique, out of 39 brain injured patients treated by phenol neurolysis or neurectomy [27]. Outcome measures were not specified. Decreased intrinsic tone was observed in all hands soon after surgery, with improvement of hygiene for all. In 13 patients, spasticity returned to its basic level within 6 months.

Adverse events: Transient soreness is almost always reported, but disappears within 5 to 10 minutes [22,24,26]. More worrying is the risk of dysesthetic pain or causalgia, which can be persistent, as described for 2 patients by Kong et al [26]. This risk, like the risk of loss of sensitivity, which is dramatic for the hand, is a high risk for mixed nerves. Although it is not mentioned by Pelissier et al, it must be taken into account in the therapeutic choices. Open surgical techniques designed to avoid these adverse effects are to our knowledge not widely used.

Summary and recommendations: except a review [18], all the studies reviewed were at level of evidence VI [19-27]. My opinion is that in spite of well-conducted study among post stroke patients, percutaneous chemical nerve neurolysis can be recommended. It is not expensive and allows concomitant treatment of a whole group of muscles. For non-sensitive nerves, this treatment is useful but for motor nerves with a sensitive component it must be used with caution. Comparative studies of neurolysis and BTX such as that by Kirazli et al for the tibial nerve are needed [28]. Intramuscular neurolysis have to be discussed with BTX which is not painful and probably more efficient. Anyway, before undertaking such local treatment, the great interest of the anaesthetic nerve blocks must be emphasized. Easy to perform with some experience, they are often essential to guide further local treatment [29].

Grade of recommendation: B

Local treatment by neuromuscular blockade with botulinum toxin (BTX)

This review covers 36 articles comprising 10 double blind placebo controlled studies, 23 open label or case report

studies, 2 reviews and 1 consensus. All but one concern BTX-A (Dysport and Botox). One concerns BTX-B [30], an open label trial of 10 patients which favours the use of BTX-B to reduce spasticity.

The use of BTX to treat post stroke spasticity is relatively recent, and reports on the subject were published after it had been used for cerebral palsy and adult dystonia. Some post stroke patients had been included in more general series [31-33], and the first placebo-controlled trial was published in 1995 but only included 12 post stroke patients and 2 upper limbs [34].

Van Kuijk et al [35], in a recent review of 4 randomised trials [36-39] and 6 observational studies which focused on upper extremity spasticity, published between 1996 and 2000, pointed out the weaknesses of most of these studies and especially as regards inclusion criteria. In most of the studies the functional prognosis factors (severity of stroke, time post stroke and comorbidity) were heterogeneous or not detailed. Nevertheless, the efficacy of BTX-A in reducing upper limb post stroke spasticity was demonstrated, although many questions remained unanswered, the main of them being the real effect of BTX-A on motricity and functional disabilities.

I – Efficacy of BTX A in reducing upper limb spasticity:

* Relevant double blind placebo controlled studies (Table 2):

- Simpson et al [36] were the first to demonstrate the reduction of upper limb spasticity among 39 patients receiving a total dose of 75, 150 or 300 U Botox versus placebo. Patients had to have had their stroke at least 9 months previously and to have had a stable clinical course for at least two months before the study. A reduction in elbow and wrist muscle tone was observed at weeks 2, 4 and 6 with BTX-A, and was significantly greater than with placebo.

- Bakheit et al [38] compared the effects of 3 doses of Dysport (500, 1000, 1500 U) vs placebo. Eighty-two patients with hemiplegic stroke and severe or moderately severe muscle spasticity, were recruited at least 3 months after stroke, and completed the study. A significant reduction in muscle tone occurred at week 4, whatever the dosage of BTX-A vs placebo, over the 16 week follow up period for the elbow and the wrist whatever the dose, and for the fingers in the 1000 U group.

- Smith et al [39] reported 21 patients who were treated with 0, 500, 1000 or 1500 U Dysport at least 1 year after a brain lesion (stroke or traumatic brain injury). BTX-A induced a significant reduction in muscle tone at week 6, whatever the dose.

- Bhakta et al [40], in a study devoted to the impact of BTX A on disability (see below), reported that BTX-A effectively reduced muscle tone with a total dose of 1000 U Dysport for all patients versus placebo.

- Richardson et al [41] reported 52 patients with spasticity of various etiologies, treated with different doses of BTX-A (Botox). At week 3, muscle tone had significantly decreased with BTX-A versus placebo.

- Bakheit et al [42] reported the effectiveness of 1000 U

Dysport in reducing spasticity of the wrist and the finger joints of 54 patients over the 16-week follow-up.

- Brashear et al [43] conducted the most important study. They reported the efficacy of BTX-A, at a total dose of 200-240 U Botox, among 122 patients who were enrolled at least 6 months after a stroke and were disabled by upper limb spasticity for hygiene or dressing, or by pain, or by mal position of the wrist or fingers. A significant reduction in muscle tone followed BTX treatment and lasted for 12 weeks.

* Open label trials or case reports devoted to post-stroke upper (+/- lower) limb

Numerous open label trials and case reports are of interest, as they throw light on specific aspects of the question and will be cited below at various points.

* **Doses and dilution:**

The choice of the right dose per muscle remains a problem. Animal and some human studies have shown that the magnitude of denervation depends on the dose of toxin [44], but the right dose is not clear from clinical trials. Different dosages were compared in three controlled studies. Two of them which concerned different doses of Dysport [38,39], failed to demonstrate any significant difference between the results for 500, 1000 or 1500 U, although they tend to be better with 1000 [38] or 1500 U [39]. In the study concerned with Botox [36], a reduction of spasticity was only observed with the highest dose (total 300 U), but the physician's global assessment response and the patients' subjective assessment indicated a significant improvement for both 300 and 75 U, but not for 150 U. In addition, some authors have suggested that low total doses such as 100 U Botox, might be effective [45].

The **BTX dilution** may also be important. Francisco et al [44] compared the efficacy of 2 commonly used dilutions of BTX-A: 100 U Botox in 1 or 2 ml of saline solution. Thirteen patients with severe spasticity at least 1 month after a stroke or TBI completed a randomised trial over 12 weeks, with an average of 417 U in the high volume group, 432 U in low volume group. Spasticity was reduced without a significant difference between the groups. However, the results tended to be better in the higher volume group.

The Table 3 shows the range of doses used for each muscle, for the studies which gave this information and in which functional improvement was observed. The usual choice of the dose needed must be guided by the clinical experience, which allow to appreciate the main muscles concerned. This includes clinical examination, information from patients and carers and occasionally electromyography.

One of the main questions remaining is to assess the different means of improving the local efficiency of BTX: dosage, dilution, and number and location of the injections. However, reducing muscle tone, as assessed by the Ashworth scale and PROM, is not the real goal of the treatment and is not important for the patient. Treatment must be assessed on the basis of motor and functional improvement. The real difficulty is to assess the precise impact of treatments on motricity and functional abilities.

II- Efficacy of BTX-A in improving motricity and functional abilities.

Global assessment scales such as Functional Independence Measurement (FIM) or the Barthel index have failed to reveal any changes, because of their inadequate sensitivity [36,38,46,47].

Upper limb motricity can be variously assessed, according to muscle strength, standard motor tasks, standard motricity scales and specific functional goals.

1-Motor strength: Besides reducing spasticity, BTX can obviously induce weakness of the muscle treated, as observed by Bhakta et al [40] for grip after treatment of the finger flexors. However an increase in the strength of muscles like flexor digitorum profundus (FDP) or superficialis (FDS), located near muscles treated with low BTX doses such as flexor carpi radialis (FCR) and flexor carpi ulnaris (FCU) was observed by Simpson [36], who suggested that a relatively low dose of BTX may reduce muscle tone sufficiently in one set of muscles to unmask function in nearby set. Pandyan et al [48] also observed a mean increase in grip after treatment of the elbow flexors and "flexor digitorum longus" (FDL) and even an increase in isotonic elbow flexors strength in 6 of the 14 patients. Usually, increased of antagonist muscle control can be expected. A trend towards improved strength of the elbow extensors was noted by Pandyan et al [48]. Rousseau et al observed a significant facilitation of wrist and fingers extensors [46]. Rodriquez et al observed a significant increase in fingers extension in 14 chronic hemiplegic patients treated with 50U Botox in both the FDP and FDS [49]. Bakheit et al [38] observed a similar effect for fingers extension in 21% of the patients in the high dose group, but also noted a decrease in 15%.

2- Motor tasks: The Nine Hole Peg Test, the only standard one used, failed to demonstrate any improvement despite reduced spasticity [41,46]. Although the work of Hurvitz et al concerned children, it is of interest. These authors tested four movements: forward reach, bilateral rhythmic movements, isometric pinch and hand tapping, up to 24 weeks after treatment, in 9 subjects with cerebral palsy or stroke [50]. They pointed out that the improvement occurred earlier for the least complex movements such as pinch force or hand tapping, and was maximal between 2 and 6 weeks. For more complex movements such as reaching tasks, the improvement occurred much later, starting at 12 weeks or later.

3- Standard motricity scales: Using the Fugl Meyer scale, Simpson et al [36] did not observe significant change. The same applied to the Frenchay Arm Test (FAT) used by Smith et al [39]. Conversely, Sampaio et al using FAT in 19 patients, noticed a significant improvement of upper limb motricity at one month after treatment with a maximum dose of 150 U Botox [51]. With the Rivermead Motor Assessment, Rousseau et al [46] observed a significant improvement in 20 patients, but Bakheit et al [38] and Richardson et al [41] did not.

4- Specific functional goals: As emphasized by many authors, it is important to identify patient-specific treatment goals [37,41,43,52] and then to assess the results of

a treatment with more specific tools. Cleaning the palm, cutting the fingers nails of the affected hand, and putting the affected arm through a sleeve are the minimal basis of the assessment used by all the authors whose objective was to study disability accurately [30,32,37,38,43,46] and then made more obvious the positive impact of the reduction of spasticity in all of these studies but one [38]. Rousseaux et al analysed the use of the affected hand in domestic activities by means of an interesting nine-item scale (from a global grasp to a complex manipulation), and some of these items revealed post treatment improvement [46]. Using an 8-item disability scale rated by the patient and carer, Bhakta et al [40] documented a significant improvement in both patient disabilities at weeks 6 and 12, and the care burden at week 6. Panizza et al observed an improvement in functional motricity through a 15-item questionnaire [53]. Brashear et al used the Disability Assessment Scale which includes 4 areas of disability: hygiene, dressing, limb position and pain, and observed a significant improvement in fulfillment of the target of treatment, which lasted for 12 weeks [43]. This study was the first to use such a disability scale as a primary outcome measure.

Finally, many authors used global subjective assessment, in which clinician and/or patients or caregivers are asked to assess their subjective impression of change after the treatment of spasticity, by means of 4 to 8 point scales [36,39,41,43,44]. The significant improvement observed at week 6 persisted at week 12 according to some authors [43], but not others [36,39]. In Francisco's study, the global rating scale at weeks 8 and 12 tended to be in favour of the high volume dilution of BTX [44].

III – Efficacy of BTX-A for pain relief

There is not much information about pain. It was one of the 4 components of the disability assessment scale used by Brashear et al [43], but was not the principal target of treatment. Three other studies mentioned the lack of significant reduction of pain [36,38,40]. In another series, BTX-A relieved pain [54], but no detail were given. Yet spasticity can lead to different kinds of pain and in particular contribute to the shoulder pain of hemiplegic patients. This pain can be relieved by treating the spasticity of the subscapularis muscle as previously done with phenol [23] or recently by us with BTX (250 U Dysport) [55].

IV- Length of efficacy and repeated treatment:

Patients were usually followed up for 12 weeks [37,39-41,43] or 16 weeks [36,38,56], and sometimes more (in one series, five months [46]). Spasticity assessed by the Ashworth scale and PROM, usually returned to baseline at week 10 or 12 [36,39,41,56] but sometimes lasted for 12 weeks [37,40,43] or 16 weeks [38]. It is interesting to observe that despite the probably limited efficacy of BTX for muscular tone, the functional improvement may persist longer, up to 3 months [38,43], 4 months [56] or 5 months [46], although this was not always the case [36,39]. Of particular interest is the open study by Lagalla et al [57], in which 28 stroke patients were treated every 3 to 5 months for 2 years or longer. The efficacy, observed on MAS,

PROM and daily living activities, was unchanged despite longer mean intervals between injections. The preliminary results reported by Gordon et al [58] on the follow up of 111 patients among those studied by Brashear et al [43] are also interesting. They received up to 3 injections of 200 to 240 U Botox, with an interval of at least 12 weeks between each one. Treatment was always considered effective without decreasing. Improvement in tone was sustained or increased, like the improvement in disability.

This raises the question of the appropriate moment for the treatment, which merits further study to assess the possibly different effects of the time lag between stroke and the treatment, and the influence of BTX on recovery. This is interesting as regards the possible effects of the reduction of spasticity on neuronal plasticity, and what might be a permanent effect of BTX on neurological recovery. This is a major question which deserves further investigation among patients with recent stroke. Although it is easier to assess the efficacy of the BTX treatment in patients whose spasticity is considered stable, it is probably much more important to treat spasticity as soon as possible to obtain the maximum recovery of motricity.

V- Which muscles should be treated? (table 3) :

The elbow, wrist and fingers flexors are the targets of treatment in almost all the studies. At the shoulder, the treatment of the pectoralis major is sometimes mentioned. We recently used BTX-A to treat the subscapularis muscle in three patients, with good results for pain, PROM and care giver impression [55]. The triceps brachii was treated in one study [50], although in our experience, spasticity of the elbow extensor is fairly often present and disabling. For the spastic hand, Palmer et al [59] reported treatment of the lumbricals in a patient with traumatic brain injury.

VI – What kind of muscle overactivity is the target of BTX treatment?

Although spasticity is the usual target of BTX treatment after stroke, other abnormal motor patterns occurring after stroke may be treated, such as dystonia or syncinesia. Van Kuijk [35] deplored the fact that spasticity was rarely well defined, and that the Ashworth scale is not a specific measure of spasticity. This is true, but in daily clinical examination it is not always easy to distinguish between spasticity and abnormal movements patterns. Then, the term of muscle over activity is often preferred, and BTX can probably be considered as a potential treatment of all types of post stroke muscle over activity. Thus, Bakheit et al [60] observed in 8 post-stroke patients, that a single injection of 500 U Dysport in the biceps brachii, reduced the upper limb associated reaction (flexion of the elbow and abduction and elevation of the shoulder), and had a good impact on walking in 7/8 patients.

VII – Place of physical therapy (PT) and occupational therapy (OT)

Two different goals for PT after BTX injection must be clearly distinguished.

The first is to enhance the results of the treatment by fa-

cilitating BTX diffusion. Hesse et al [37] who published the only study on this topic demonstrated that electrical stimulation of the treated muscles three times a day for 3 days after an injection significantly enhanced the effect of BTX. In the other studies, stretching and strengthening are sometimes mentioned as a combined treatment, but were not specifically evaluated.

The second goal of PT is to improve motricity and functional abilities. For this, different treatment options should be considered: stretching and mobilizing, positioning programme, facilitation of the opposing and neighbouring muscle groups, occupational therapy and also patient education, with home exercise programmes [61,62]. Such treatment must be adjusted to the goals of BTX treatment, which are obviously different when the objective is passive range of motion and care burden improvement, and when it is increasing motricity and functional abilities.

The European Consensus certainly stated that "before using BTX, the team must ensure that an appropriate rehabilitation management programme is in place and available post injection" [63], but such a programme have not be evaluated. Conversely, it seems that BTX plus physiotherapy substantially reduces spasticity more than physiotherapy alone, for a small additional cost [64].

Apart from other investigations, the authors of an interesting and original study conducted among cerebral palsy and traumatic brain injury patients demonstrated that the reduction of spasticity after BTX injection increased the normal response of cortical somatosensory evoked potentials (SEPs) after stimulation of the tibial or median nerves [65]. The possible link between spasticity and sensitivity is interesting.

Summary and recommendations: 8 studies reviewed were at level of evidence II (IIa [36-40, 42-44] or IIb [41]) and allow to recommend BTX as a local treatment effective to reduce post stroke spasticity. Many open trials or cases series at level of evidence VI [30-33, 45-51, 53-62] add interesting arguments. My opinion is that BTX is a very interesting treatment which has markedly changed the approach to the treatment of spastic disorders. Serious adverse events have never been observed in the upper limb after its use; transient soreness sometimes occurs, but no swallowing disorders have been observed. The problem now, is not to assess its efficacy for spasticity itself, but its place in improving functional abilities. Three ways should be explored: the use of higher BTX doses than those published, to treat very severe and diffuse spasticity, the means to improve its efficacy (doses, dilution, site of injection, physiotherapy) and the changes induced in recovery especially when it is used soon after stroke.

Grade of recommendation: A

CONCLUSION:

Each of the pharmacological treatments reviewed here may be useful and is worth discussing in relation to each individual situation. They can be used separately, or together, or combined with physical therapy or surgery. The choice of treatment depends on individual goals. Two main situations must be taken into account:

- firstly, severe hemiplegia with dramatically impaired upper limb motor command. In such cases, spasticity is often disabling because of the spontaneous position of the upper limb, which is disabling for washing and dressing, unaesthetic and painful. Treatment must reduce the spasticity markedly, without fear to be excessive while aiming to avoid adverse events.

- secondly, when recovery of motor control is good or relatively good, spasticity may limit functional movements. An attentive examination is necessary to determine, with the patient and carers, the exact goals of the treatment. Usually, local treatments are preferred, the fear here being to induce an excessive impairment of strength.

As a guide to treatment, the practice of an anaesthetic block is very helpful.

None of these treatments is exclusive, on the contrary, they are complementary and all combinations can be considered.

QUESTIONS FOR DISCUSSION:

*Is there still any place for:

chemical intramuscular neurolysis with alcohol or phenol ?
chemical nerve neurolysis with alcohol or phenol ?

*How can the efficacy of BTX be increased?

(doses, dilution, choice of the sites and number of injections...)

*What kind of physical therapy and occupational therapy should be recommended after injection? *Are standard programmes feasible?

Author	Level of evidence	Patients	Product	Muscle/nerve target	Outcome measures	Main outcomes
Keenan 1987	VI	20 TBI	Phenol 5 % In glycerine	Ulnar nerve (open nerve block)	Not described	-early postoperative decrease in intrinsic tone in all hands - adverse event : one hand developed an intrinsic deformity. 7 hands had limited improvement, myostatic contractures of the intrinsic muscles. - 2 wound complication – 1 infection -13 hands had return of spasticity in 6 months - improved function in 6/21.
Hecht 1992	VI	11 stroke, 2 TBI	Phenol 6,7 %	Subscapularis m.	PROM	- immediate significant improvement in external rotation, flexion and abduction - pain appeared to diminish
Pelissier 1993	VI	13 patients (stroke and TBI)	Alcohol 60 %	Pectoralis major m.	- Ashworth -Angle of tonic response	- immediate marked reduction of spasticity in 10/13 - effect lasted for 2 months - improvement of the sympathetic reflex syndrome for all, lasting 3 months
Pelissier 1993	VI	6 patients	Alcohol 60 %	Median nerve	- Ashworth	- immediate decrease of spasticity 6/6, lasted for 4/6 until D 60, for 2/6 until D 120 - no side effects.
Kong 1999	VI	20 stroke	Alcohol 50 %	Musculocutaneous nerve percutaneous injection	MAS PROM Motor strength	- Significant reduction in MAS at 4 weeks - Significant improvement in PROM at 4 weeks - No change in strength - 7/14 improved walking balance - relief of shoulder pain in 4/5 patients - Effect lasted for 6 months
Kong 2002	VI	30 stroke	Alcohol 50 % Mean vol. 6 ml	FCU, FCR, FDS, FDP, FPL	MAS PROM	Significant change in MAS and PROM at 4 weeks Effect lasted for 6 months

Table 1: Percutaneous alcohol or phenol neurolysis for post stroke upper limb spasticity

Author	Patients	Product	Muscle	Treatment algorithm	Outcome measures	Main outcomes	Length of follow up
Simpson 1996	39 stroke	Botox	BB FCR;FCU	4 groups - low dose (75 U) - Medium dose (150 U) - High dose (300 U) - Placebo	Ashworth Global assessment of spasticity scale Care giver dependency FIM - Fugl Meyer scale	- reduction in tone for all vs Placebo only signif. for high dose at weeks 2,4,6 - improvement of GASS for high and low doses at weeks 4 and 6 - improvement of grip with low doses - no other change	16 weeks
Hesse 1998	24 stroke	Dysport ± Elect stim.	BB, Brachialis	1000 U + Elect.stim 1000 U Placebo + Elect.stim Placebo	- Ashworth - Limb position at rest - Care difficulties	-No signif reduction in tone Indicative reduction of elbow spasticity (better with BTX + elect stim) - No improvement of limb position - Signif improvement for cleaning the palm with stim elect (whether BTX or Placebo)	12 weeks
Bakheit 2000	82 stroke	Dysport	Biceps brachii FCR, FCU FDP, FDS	Placebo versus 1 of 3 doses 500 U/1000 U/1500 U.	- MAS (elbow, wrist, fingers) - AROM – PROM - pain - Barthel - Rivermead	- all 3 doses resulted in significant reduction in MAS in all joints at week 4 - at week 16, idem for elbow and wrist ; reduction with 1000 U/finger - No significant improvement of functional assessment (1000 U seemed best).	16 weeks
Bhakta 2000	40 stroke	Dysport	Biceps brachii Brachio radialis FDS, FDP, FCU	1000 U/ patient	- an 8-item disability scale rated by patient or carer -muscle power – grip - MAS - PROM - Pain	- significant improvement of disability, at week 6 - significant reduction in carer burden at weeks 6 and 12 - significant reduction of forearm flexor spasticity for up to 12 weeks - slight reduction of elbow flexor spasticity - no change in arm pain -reduction of grip.	12 weeks

Table 2 (1): Randomised double blind controlled trials of Botulinum Toxin for upper limb post stroke spasticity

Author	Patients	Product	Muscle	Treatment algorithm	Outcome measures	Main outcomes	Length of follow up
Smith 2000	21 patients (19 stroke)	Dysport	2/3 of the BTX dose above the elbow 1/3 below	4 groups - 500, 1000, 1500 U - Placebo	PROM MAS Frenchay arm test Time to dress Finger curl Global clinical assessment	- Signif reduction in tone at finger and wrist - Signif improvement of PROM at wrist - Signif improvement of finger curl - Results signif at week 6, lost by week 12 - Signif improvement of the global rating scale - No signif difference between dose-groups (slightly better with 1500 U)	12 weeks
Bakheit 2001	58 patients	Dysport	5 muscles	1000 U vs placebo	MAS PROM Barthel Goal attainment subjective evaluation (Patient and Physician)	- Signif reduction in the summed MAS at week 4 up to week 16 - No difference for PROM, pain, goal attainment or Barthel at week 4 - Improvement elbow PROM at week 16 - Signif improvement of global assessment of benefit by patients at week 16	16 weeks
Brashear 2002	126 stroke	Botox	FCR, FCU For all FDP, FDS ± FPL – adductor pollicis	50 U per muscle ± 20 U per thumb muscle Total 200-240 U	- a 4 points disability assessment scale - muscle tone (Ashworth) - Global assessment scale - at 1,4,6,8,12 weeks	- significantly greater improvement in the principal target of treatment - lasted for 12 weeks - significant reduction of spasticity at all follow up visits. - significant higher global assessment - no specific adverse event.	12 weeks

UL = upper limb ; FCR = Flexor Carpi Radialis ; FCU = Flexor Carpi Ulnaris ; FDP = Flexor Digitorum Profundis ; FDS = Flexor Digitorum Superficialis ; FPL = Flexor Pollicis longus ; BB = Biceps brachii ; MAS = Modified Ashworth Scale ; FIM = Functional Independence Measurement ; AROM = Active Range Of Movement ; PROM = Passive ROM

Table 2 (2): randomised double blind controlled trials of Botulinum Toxin for upper limb post stroke spasticity

	DYSPORT Units	BOTOX Units		DYSPORT Units	BOTOX Units
Pectoralis major		50-75 (Hurvitz) 30-100 (Rousseau)	Flexor Digitorum Superficialis	300 (Bhakta 00) 125 (Hesse)	50 (Brashear 02 – Rodriquez) 10-50 (Wang) 25 (Sampaio) 20 (Girlanda)
Subscapularis	250 (Yelnik)		Flexor Digitorum Profundus	200 (Bhakta 00) 125 (Hesse)	50 (Brashear 02 – Rodriquez) 10-30 (Wang) 25 (Sampaio) 15-20 (Viriyavejakul) 20 (Girlanda)
Biceps Brachii	500 (Bakheit 02) 300 (Bhakta 00) 250 (Hesse)	50-200 (Simpson) 100 (Hurvitz) 50-100 (Wang) 30-40 (Viriyavejakul)	Flexor Pollicis Longus		25 (Sampaio) 20 (Brashear 02) 20 (Girlanda)
Brachio radialis	100 (Bhakta 00)	20 (Girlanda) 15-20 (Viriyavejakul)	Flexor Pollicis Opponans		25 (Sampaio)
Brachialis	250 (Hesse)		Lumbrical		12-15 each (Palmer)
Flexor Carpi Radialis	125 (Hesse)	15-60 (Simpson) 50 (Brashear 02 – Hurvitz) 20-40 (Wang) 30 (Girlanda 97) 25 (Sampaio) 15-20 (Viriyavejakul)	Pronator Teres		15-35 (Rousseau) 30 (Hurvitz) 15-20 (Viriyavejakul)
Flexor Carpi Ulnaris	100 (Bhakta 00) 125 (Hesse)	50 (Brashear 02- Hurvitz) 20-40 (Wang) 10-40 (Simpson) 30 (Girlanda 97) 25 (Sampaio) 15-20 (Viriyavejakul)			

Table 3: Botulinum Toxin Doses for which motor or functional improvement was observed

LEVEL OF EVIDENCE

2	Gracies 97	I
3	Rode	I
4	Pinder	I
5	Ketel	IIa
6	Katrak	IIa
7	Wagstaff	I
8	Bes	I
9	Milanov	VI
10	Gelber	VI
11	Meythaler 01a	IIa
12	Emery	I/
13	Francisco 01a	I/
14	O'Brien	I/
15	Sampson	I/
16	Meythaler 01b	IIa
17	Francisco 01b	VII
18	Gracies 97	I
19	Tardieu	VI
20	Braun	VI
21	Garland 82	VI
22	Pelissier	VI
23	Hecht	VI
24	Kong 99	VI
25	Keenan 90	VI
26	Kong 02	VI
27	Keenan 87	VI
28	Kirazli	IIa
29	Filipetti	VI
30	Brashear 03	VI
31	Dunne	VI
32	Bhakta 96	VI

33	Pierson	IIb
34	Grasko	IIb
35	Van Kuijk	I
36	Simpson 96	IIa
37	Hesse 98	IIa
38	Bakheit 00	IIa
39	Smith 00	IIa
40	Bhakta 00	IIa
41	Richardson	IIb
42	Bakheit 01	IIa
44	Francisco 02	IIa
46	Rousseau	VI
47	Barnes	VI
48	Pandyan	VI
49	Rodriguez	VI
50	Hurvitz	VI
51	Sampaio	VI
52	McGuire	VII
53	Panizza	VI
54	Wang	VI
55	Yelnik	VI
56	Girlanda	VI
57	Lagalla	VI
58	Gordon	VI
59	Palmer	VI
60	Bakheit 02	VI
61	Albany	VI
62	Stark	VI
63	Ward	I
64	Wallesch	VI
65	Park	VI

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A CRITICAL REVIEW OF NEUROMUSCULAR ELECTRICAL STIMULATION FOR TREATMENT OF UPPER LIMB MOTOR DYSFUNCTION IN HEMIPLEGIA (R12)

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ABSTRACT

The purpose of this review is to critically assess the clinical efficacy of neuromuscular electrical stimulation (NMES) in treating upper limb motor dysfunction in hemiplegia. Three distinct applications are reviewed in the areas of motor relearning, shoulder dysfunction and neuroprostheses. Assessment of clinical efficacy and recommendations regarding clinical implementation are based on the weight of published scientific evidence. With respect to motor relearning, evidence supports the use of NMES to facilitate recovery of muscle strength and coordination in hemiplegia. However, effects on activities of daily living (ADLs) are uncertain. With respect to shoulder dysfunction, NMES decreases shoulder subluxation, at least in the short-term. However, effects on shoulder pain and ADLs are uncertain. With respect to neuroprosthesis systems, clinically deployable upper extremity systems must await the development of more sophisticated control methods and greater fundamental understanding of motor dysfunction in hemiplegia. In summary, the application of NMES for motor relearning and shoulder dysfunction are ready for more rigorous scientific and clinical assessment via large, multicenter, randomized clinical trials. However, additional investigations are needed to demonstrate the clinical feasibility of neuroprostheses applications.

Key Words: FES, Upper limb, hemiplegia, Stroke, Rehabilitation

Stroke is the leading cause of activity limitation among older adults in the United States. More than 700,000 strokes occur each year,¹ with a prevalence of approximately 4 million.² Nearly a third of all stroke survivors will have significant residual limitations in activities of daily living and mobility with older individuals generally experiencing slower recovery.^{3, 4} Prevention of complications of immobility, implementation of compensatory strategies, facilitation of psychosocial adjustment to activity limitation, and community reintegration are central to the rehabilitation management of persons with hemiparesis. However, the devastating effects of persistent neurologic impairment on activity limitation and QOL continue to persist for many stroke survivors.

The purpose of this review is to critically assess the clinical efficacy of neuromuscular electrical stimulation (NMES) in treating upper limb motor dysfunction in hemiplegia at the level of motor impairment and activity limitation. The World Health Organization defines "impairment" as "problems in body function or structures such as significant deviation or loss."⁵ Hemiparesis is a major impairment following stroke. The World Health Organization defines "activity" as "the execution of a task or action by an individual," and "activity limitation" as "difficulty an individual may have in executing activities."⁵ The terms "disability"⁶ and "functional limitation"⁷ are used in different sources to convey concepts similar to activity limitation.

Three distinct applications are reviewed in the areas of motor relearning, shoulder dysfunction and neuroprostheses. Clinical significance of these applications and relevant background and definitions are presented in greater detail in their respective sections. Assessment of clinical efficacy and recommendations regarding clinical implementation are based on the weight of published scientific evidence with greatest weight placed on blinded randomized clinical trials and progressively less weight on open label pre-test post-test designs, case series and case reports as described by Greenbough (Table 1).⁸ Assessments are based on full papers published in English language peer reviewed scientific journals. Studies published in abstracts and meeting proceedings do not provide sufficient methodological information to allow critical appraisal of the study results and are not included in this review, except in the context of discussion of future investigations. The level of evidence for each assessment or recommendation is then graded according to Shekelle (Table 2).⁹

NEUROMUSCULAR STIMULATION FOR MOTOR RELEARNING

Background

Motor relearning is defined as "the recovery of previously learned motor skills that have been lost following localized damage to the CNS."¹⁰ Evolving basic science and clinical studies on central motor neuroplasticity now support the role of active repetitive movement training of the hemiparetic limb to enhance motor relearning.¹¹ In spite of the growing evidence that motor relearning after stroke is activity dependent, large segments of stroke survivors are not able to take part in this strategy due to the severity of their hemiparesis and the evolving healthcare environment.¹² However, if active repetitive movement training facilitates motor relearning, then NMES-mediated repetitive movement training may also facilitate motor relearning. Two types of NMES are available. The first is cyclic NMES, which electrically activates paretic muscles at a set duty cycle for a preset time period. The patient is a passive participant and does not assist the NMES by volitionally contracting the muscle during stimulation. The second type encompasses various forms of NMES in combination with biofeedback. This NMES strategy attempts to couple afferent feedback during NMES induced contraction with cognitive intent to further enhance motor relearning.

Critical Review of Controlled Trials

Cyclic Neuromuscular Electrical Stimulation. Four randomized clinical trials investigating the efficacy of cyclic NMES in enhancing upper limb motor relearning are published in the literature.¹³⁻¹⁷ A summary of these studies appears in table 3. Please note that the two studies by Sonde et al. refer to the same study with the 1998 publication¹³ reporting end of treatment results and the 2000 publica-

tion¹⁴ reporting 3-year follow-up results. All four studies demonstrate improved outcomes in motor impairment at end of treatment with mild to moderately impaired subjects benefiting most. Among the three studies that provide follow-up data, the two acute stroke studies report enduring effect,^{15,16} while the one chronic study does not.¹⁴ All four studies evaluate functional ability. However, only two of these report improvements at end of treatment,^{16,17} and the one study with follow-up data demonstrates no enduring effect on functional ability.¹⁶

The strengths of these studies rest on their randomized designs; however, numerous methodological limitations make the study results difficult to interpret. Two of four studies are not blinded.^{13,14,17} Thus, evaluator bias cannot be ruled out. Of the two blinded studies, only one is double blinded.¹⁵ Thus, placebo effect cannot be ruled out. Three of four studies have unequal treatment intensity where the treatment group receives NMES and “therapy,” while the control group receives only “therapy.”^{13,14,16,17} Thus, it is unclear whether the reported benefit is due to NMES or increased intensity of treatment. Only one study reports the total number of patients screened.¹⁶ Thus, generalization of results is difficult to assess. Of the two studies with follow-up data, the one study with a significant drop-out rate does not use intention-to-treat analysis.¹⁵ Thus, the confounding effect of selective drop-out cannot be ruled out.

Biofeedback and Neuromuscular Electrical Stimulation.

Coupling afferent feedback during contraction with patient intent may enhance the motor relearning effect of NMES mediated active repetitive movement training. Repetitive movement training mediated by cyclic NMES requires minimal to no cognitive or “efferent” investment by the user. Thus, it is not surprising that for stroke survivors with some volitional activation of finger and wrist extensors, volitional active repetitive movement training is reported to be superior to cyclic NMES in facilitating motor recovery.¹⁸ A number of methods for providing afferent feedback and NMES induced repetitive movement therapy are available. The simplest is to provide EMG biofeedback therapy and NMES therapy separately, but as part of an integrated treatment protocol.¹⁹ A second method directly links joint position with NMES. Once the subject reaches a preset threshold on a joint position feedback apparatus, NMES is initiated.²⁰ A third method is similar to the second, but instead of using joint position, subject’s own EMG signal is used to trigger or initiate the NMES.^{21,22} These techniques may be applied to patients who can partially activate their paretic muscles, but are unable to generate sufficient muscle contraction for adequate exercise or functional purposes. Thus, joint position or EMG triggered NMES facilitates patterned, repetitive, volitionally initiated exercises of the hemiparetic limb, and provides cutaneous, proprioceptive and electrical stimulation feedback time locked to each attempted movement.

Five controlled trials using EMG biofeedback and NMES or position/EMG triggered NMES for upper limb motor relearning are published in the literature.^{20,23-26} A synthesis of these studies is shown in table 4. All five studies demonstrate

improved outcomes in motor impairment at end of treatment. In the one study with follow-up data the effect is enduring after 9-mo of follow-up.²³ In the one study that evaluates functional ability, improved outcome is noted.²⁴

Unfortunately, as with the cyclic NMES studies, numerous methodological deficiencies limit the interpretation of the results. All studies use small sample sizes. Thus, studies lack sufficient power to detect small, but clinically important differences. Four of the 5 studies do not include follow-up evaluations.^{20,24-26} Thus, the long-term effect of NMES on motor impairment cannot be assessed. The one study with long-term follow-up does not use a randomized design.²³ None of the studies report the total number of potential subjects screened to arrive at their study population. Thus, generalizability of results is difficult to assess. Only 1 of 5 studies²⁴ uses blinded assessments. Thus, evaluation bias cannot be ruled out. None of the studies are double-blinded. Thus, placebo effect cannot be ruled out. In all studies, demographic or baseline differences between groups are present or differences cannot be assessed. Thus, confounding effect of these factors cannot be ruled out. Finally, the one study that reports improvements in functional ability has a very small sample size and uses a modified version of the self care component of the Functional Independence Measure with unknown psychometric properties.²⁴ Thus, the effect of the intervention on functional ability cannot be assessed.

Systematic Review

There is one systematic review²⁷ that explores the effect of cyclic and EMG/biofeedback initiated NMES on hemiparetic upper limb motor function. The review includes 6^{13-16,20,24,25} of the 9 studies described above. Three studies are not included. One was published after the review,²⁶ one was not a randomized clinical trial²³ and one used “electrical acupuncture.”¹⁷ The methodology quality is assessed systematically by two independent raters. The reported outcomes are examined to evaluate the effect and to identify a possible relationship with patient characteristics, method of stimulation and methodological quality. Methodological scores range from 7 to 16 (maximum 19). All 6 studies evaluate motor impairment with 4 showing a positive treatment effect. Two studies evaluate hemiparetic arm specific activity limitation with 1 showing a positive treatment effect. Subgroup analyses in 2 studies suggest a better response to stimulation in less severely affected patients. The study concludes that “The quantitative review suggests a positive effect of electrical stimulation on motor control [motor impairment], whereas no conclusions can be drawn with respect to function ability [activity limitation].”

Conclusions and Recommendations

Despite the numerous methodological limitations of controlled trials to date, the weight of the scientific evidence still suggests that NMES reduces upper limb motor impairment in hemiplegia (A). However, at this time there is no compelling evidence that the observed improvements in motor impairment is enduring or that the effect translates into clinically relevant improvements in hemiparetic arm

specific activity limitation (B). There is also no compelling evidence that joint position or EMG mediated NMES is superior to cyclic NMES since there are no studies that directly compare these two types of NMES paradigms (C). Future investigations should address issues on two fronts. First, the effect of NMES on motor relearning and impact on clinical outcomes should be confirmed by addressing the methodological limitations of prior studies. Future studies should be large, multicenter, placebo controlled, randomized clinical trials. Studies should carefully define the subject population including their stroke characteristics, identify potential confounds, and evaluate immediate and long-term outcomes using valid and reliable outcome measures. The second front for future investigations is refinement of stimulation technique to maximize patient compliance and clinical outcomes. To decrease the discomfort of transcutaneous NMES, ease donning and doffing of the system and maximize reliability and repeatability of stimulation, an intramuscular system should be explored.^{28, 29} In order to maximize cognitive investment from patients an EMG-controlled NMES system, which requires that patients initiate, maintain and terminate their EMG signals in order to initiate, maintain and terminate the NMES should be developed.³⁰ Future studies should also investigate more sophisticated proxies for cognitive intent such as cortical signals.³¹ Finally, basic studies should investigate mechanisms and demonstrate that therapeutic effects are due to neuroplastic processes.

NEUROMUSCULAR STIMULATION FOR TREATING SHOULDER DYSFUNCTION IN HEMIPLEGIA

Background

Shoulder pain is a common complication in hemiplegia with a prevalence of 34% to 84%.^{32, 33} Many causes of shoulder pain in hemiplegia have been postulated including adhesive capsulitis,³⁴ impingement syndrome,³² complex regional pain syndrome,³⁵ brachial plexopathy,³⁶ and spasticity.³⁵ However, one of the most commonly cited cause of shoulder pain in hemiplegia is shoulder subluxation.^{32, 35, 36} Shoulder subluxation is common in hemiplegia with a reported incidence as high as 50% within the first year of stroke among severely impaired patients.³⁵ Although frequently hypothesized, the relationship between shoulder subluxation and shoulder pain in hemiplegia remains controversial.³⁷ However, documented correlations between subluxation and other types of painful shoulder pathology suggest that subluxation plays a role in their genesis.^{32, 35, 36} Despite the uncertain relationship between shoulder subluxation and pain, treatment of subluxation continues to be the standard of care in many rehabilitation facilities. Unfortunately, the available options for preventing and treating shoulder subluxation are limited. Arm boards and lap trays have not been shown to be effective and may lead to over correction of inferior subluxation predisposing the affected shoulder to impingement syndromes. The use of slings remains controversial because they may cause lateral subluxation, contribute to the deleterious effects of joint immobilization or promote undesirable synergistic patterns

of muscle activation. A variety of slings are available but none have been shown to uniformly provide full joint reduction as an orthotic, provide long-term therapeutic benefit or reduce shoulder pain.

Critical Review of Controlled Trials

The lack of effective interventions for treating shoulder dysfunction in hemiplegia has prompted investigators to evaluate the clinical efficacy of electrically stimulating the muscles surrounding the glenohumeral joint to reduce shoulder subluxation and pain. A synthesis of nine controlled clinical trials of NMES is shown in table 5.³⁸⁻⁴⁶ Please note that the two publications by Wang et al. include separate trials for acute and chronic stroke survivors and the two studies are reporting different outcomes from the same study.^{45, 46} Seven studies evaluate NMES as a treatment modality,^{38, 39, 41, 43-46} one evaluates prevention⁴² and one evaluates a combination of treatment and prevention.⁴⁰ Five studies evaluate acute stroke survivors,^{40-42, 44-46} two studies evaluate combination of acute and chronic stroke survivors^{38, 39} and two studies evaluate chronic stroke survivors.^{43, 45, 46}

Radiographic subluxation is most consistently evaluated. Eight of nine studies^{38, 40-46} evaluate radiographic inferior glenohumeral subluxation and seven of these^{38, 40-46} report improvements. The six of seven trials that demonstrate significant effect on subluxation include only acute stroke survivors^{40-42, 44, 45} or a combination of acute and chronic stroke survivors.³⁸ Among these, only two report sustained improvements beyond end of treatment.^{40, 41} A more recent trial of chronic stroke survivors reports no significant effect on inferior subluxation.⁴⁵ The one trial of chronic stroke survivors reporting significant effect by stressing or loading the hemiparetic upper limb.⁴³ Without this stressing, there is no significant difference in subluxation between treatment and control groups.

Other commonly evaluated measures include pain-free passive range of motion (ROM), motor impairment using a standardized measure and resting shoulder pain. Six of nine studies^{39-42, 46} evaluate pain-free passive range of motion. Significant and sustained improvement in pain-free ROM in the treatment group compared to controls is reported in only one study.⁴¹ In two studies,^{39, 40} improvements are noted only using within group analyses. That is, the authors report significant changes in pain-free ROM in the treatment group compared to baseline using paired statistics, but not in the control group. Three studies report no significant effect. Six of nine studies evaluate motor impairment using a standardized measure.^{40-42, 44, 46} Two acute studies report improvements at end of treatment and at follow-up.^{41, 46} One acute study demonstrates improvement at end of treatment, but not at follow-up.⁴⁰ Three studies (two acute and 1 chronic) report no improvements in motor impairment.^{42, 44, 46} Two treatment and one prevention studies evaluate shoulder pain at rest. The treatment studies report improvements while the prevention study does not.

As with NMES for motor relearning, numerous methodological limitations make these results difficult to interpret. Seven of nine studies use small sample sizes.^{39, 40, 42-46}

Thus, studies lack sufficient power to detect small, but clinically important differences. Consequently, Wang et al.⁴⁵ uses within-group analysis to show positive effect on subluxation. Similarly, Faghri et al.⁴⁰ and Leandri et al.³⁹ use within-group analysis to show positive effect on pain-free ROM. None of the studies report the total number of potential subjects screened to arrive at their study population. Thus, generalizability of results is difficult to assess. Only three of nine studies are blinded.^{38, 39, 42} Thus, evaluation bias cannot be ruled out in most studies. Only one study is double-blinded.³⁹ Thus, placebo effect cannot be ruled out in most studies. In the one double-blinded study, sample size is too small to make any definitive statistical statements. Chantrain et al.⁴¹ reports the largest study (115 subjects) to date with the longest follow up (24-mo) with a wide range of outcome measures including resting pain, pain free-active and passive ROM, radiographic subluxation and motor impairment. However, the study is not blinded and randomization is not used to allocate treatment groups. Thus, evaluator bias, placebo effect and unequal groups contributing to the observed effects cannot be ruled out. Furthermore, in the critical area of "pain," resting pain and pain-free active and passive ROM are combined in a single composite measure. While the approach may have some clinical relevance, from a scientific point of view it is not possible to assess the effects of the intervention on each variable separately.

Systematic Reviews

Two meta-analyses that evaluate the efficacy of NMES for the treatment of hemiplegic shoulder pain are reported in the literature. The Cochrane review⁴⁷ assesses 4 studies^{13, 39, 40, 42} and concludes that NMES improves pain-free passive ROM and reduces subluxation, but does not improve shoulder pain or motor impairment. Ada and Foongchomechey⁴⁸ includes 7 studies^{38, 40, 42, 43, 45, 46} to assess the effects of NMES on hemiplegic shoulder pain as a function stroke acuity. They conclude that NMES reduces or prevents subluxation in the acute phase, but not in the chronic phase. Similarly, they conclude that NMES improves motor impairment in the acute phase, but not in the chronic phase. Finally, they conclude that NMES does not improve passive lateral pain-free ROM in the acute phase, although there is some evidence that it may improve active pain-free range of motion in the chronic phase. The differences in conclusion between the 2 meta-analyses are likely due to the differences in inclusion criteria used to accept specific studies in the respective studies.

Conclusions and Recommendations

Despite the above methodological limitations, the weight of the evidence suggests that NMES reduces shoulder subluxation among acute stroke survivors, at least in the short-term (A). NMES does not appear to have significant effect on subluxation among chronic stroke survivors (A), although additional studies are needed to further explore this question. Similarly, NMES improves motor impairment among acute stroke survivors, but not among chronic stroke survivors (A). The effect of NMES on shoulder pain

is less clear. If pain-free passive ROM is an appropriate proxy for shoulder pain, the effect of NMES on shoulder pain is equivocal at best (B). Pain at rest as a proxy for shoulder pain is difficult to assess in view of the small number of studies evaluating this measure and their methodological limitation.

As with the application of NMES for motor relearning, future investigation should be directed at issues on 2 fronts. First, the effect of NMES on shoulder subluxation and impact on pain, motor impairment and activity limitation should be confirmed by addressing the methodological limitations of prior studies. Future studies should be large, multi-center, blinded, randomized clinical trials. Subject population should be clearly defined as acute or chronic, and their stroke characteristics and potential confounds should be presented. The object of the study should be clearly defined as "treatment" or "prevention." In order to remain clinically relevant, reduction or prevention of pain should be the principal goal of these studies. The second front for future investigations is refinement of stimulation techniques to maximize patient compliance and clinical outcomes. Despite the evidence for clinical benefit, the clinical use of transcutaneous NMES has been limited for several reasons. First, stimulation of cutaneous nociceptors cannot be avoided resulting in stimulation-induced pain that limits tolerance and compliance. Second, activation of deep muscles cannot be achieved without stimulation of more superficial muscles. Third, stimulated muscle contraction cannot be precisely titrated. Fourth, clinical skill is required to place the electrodes and adjust stimulation parameters to provide optimal and tolerable treatment. Finally, the specific muscle and the number of muscles for optimal shoulder reduction are not known. A potential solution is intramuscular NMES systems, which can be placed percutaneously⁴⁹ or injected²⁹ into the target muscle. These systems are presently undergoing clinical trials.^{50, 51}

NEUROMUSCULAR ELECTRICAL STIMULATION FOR UPPER LIMB MOTOR NEUROPROSTHESIS IN HEMIPLEGIA

Background

A neuroprosthesis is defined in this review as the use of NMES to activate or substitute for paralyzed or paretic muscles in precise sequence and intensity to assist in the performance of activities of daily living. Although considerable advances in neuroprostheses technology has occurred over the last two decades for persons with spinal cord injury, the application of this technology for persons with hemiplegia has been more limited. The available data on the clinical feasibility of NMES for motor neuroprosthesis in hemiplegia are critically reviewed followed by perspectives on future developments and directions.

The objective of a hand neuroprosthesis system is to provide hand grasp and release in order to reduce reliance on assistance from others, need for adaptive equipment, need to wear braces or other orthotic devices and time required performing functional tasks. In view of the success of the hand neuroprosthesis in tetraplegia,⁵² it is reasonable to apply the technology to persons with hemiplegia.

Critical Review of Clinical Reports

The review of the literature reveals five full length articles in English language peer-review journals that evaluate the effectiveness of a hand neuroprosthesis for enhancing the upper limb function of stroke survivors.⁵³⁻⁵⁷ All studies have limited sample sizes and use open label designs with performance evaluation with and without the neuroprostheses (Level of evidence: VI).

The two earlier reports^{53,54} evaluate similar systems among neurologically stable chronic stroke survivors. Both use transcutaneous NMES to open the hand while closing is mediated by termination of stimulation and subject's own volitional ability. The intensity of stimulation is controlled with a position transducer mounted on the contralateral non-paralyzed shoulder. Both studies report improved manipulation of objects with the stimulation compared to without. However, the feasibility of the device in providing everyday functional ability is not assessed. In addition, Merletti et al⁵⁴ report that specific tasks require considerable amount of mental concentration, and in several cases voluntary effort to control the paretic limb produces tremors, spasticity and erratic shoulder movement, which results in reduced performance. More recent studies using a hybrid surface electrical stimulation/brace system report mixed results with one demonstrating no functional benefit⁵⁵ and the other reporting limited ability.⁵⁷ A recent evaluation of a percutaneous intramuscular electrical system⁵⁶ fails to demonstrate any functional benefit. The latter study explicitly indicates that the stimulation is able to open and close the hand as long as the paretic arm is in a resting position. However, when functional tasks are attempted, performance is significantly reduced due to associated reactions and co-contractions.

Conclusions and Recommendations

Although the above studies are preliminary in nature, several conclusions can be drawn. Transcutaneous and intramuscular NMES systems are able to open spastic hemiparetic hands as long as subjects remain relaxed and do not assist the NMES. However, when subjects try to assist the NMES or to use the system for functional tasks, significant decline in performance may occur. At this time, there is no compelling evidence that an upper limb neuroprosthesis based on present technology is effective in improving the hand function of stroke survivors [Grade of recommendation: C]. Future systems will require control paradigms that provide smooth, unencumbered control of arm movement. This will likely require cortical control, closed loop feedback and methods to rapidly modulate undesired muscle activity such as spasticity, co-contractions and associated reactions.

CONCLUSION

The principal goal of the rehabilitation management of persons with hemiplegia is to maximize quality of life. While quality of life is clearly influenced by a wide range of variables including social, emotional, psychological, vocational and educational factors, the persistent neurological impairment after injury to the central nervous system

remains a powerful reminder and determinant of one's physical disability and handicap.

NMES may have an important role in improving the motor function of stroke survivors. Active repetitive movement training mediated by cyclic and EMG-mediated NMES may facilitate the motor recovery of stroke survivors. Multi-center, double-blinded randomized clinical trials should be pursued to confirm the motor relearning effects of NMES and define appropriate prescriptive specifications. Future systems are likely to employ intramuscular stimulation mediated by more sophisticated proxies for cortical intent. Shoulder subluxation and pain are likely to remain significant problems among stroke survivors. Encouraging early results with transcutaneous NMES techniques should be confirmed in larger randomized, multicenter clinical trials. Neuroprostheses systems, which substitute for paralyzed muscles may provide significant improvements in hand function for persons with chronic hemiplegia. However, implementation of clinically viable systems will likely require additional technical developments. Clinically deployed systems are likely to be cortically controlled and fully implanted using advanced techniques to turn off unwanted muscle activity as well as to activate weak muscles.

After decades of development, the clinical utility of sophisticated electrical neuromuscular stimulation systems may be realized. However, in view of the dynamic nature of the present health care environment, the future of NMES technology is still difficult to predict. By necessity, scientists and clinicians must continue to explore new ideas and improve upon the present systems. Components will be smaller, more durable and more reliable. The issues of cosmesis and ease of donning and doffing will require systems to be percutaneous for temporary interventions and fully implanted for neuroprosthetic systems. Control issues will remain critical for both motor relearning and neuroprosthetic applications, and the implementation of cortical control will dictate the nature of future generations of NMES systems.

Finally, consumers will direct future developments. In the present health care environment where cost has become an overwhelming factor in the development and implementation of new technology, the consumer will become one of technology's greatest advocates. The usual drive toward greater complexity will be tempered by the practical issues of clinical implementation where patient acceptance is often a function of a tenuous balance between the "burden or cost" associated with using a system and the system's impact on the user's life.

Rating of Study Design	Type of Study
I	Systematic review and or meta analysis (where statistical techniques are used to pool the results of included studies)
IIa	Randomized controlled trial (with definitive results that do not overlap the threshold clinically significant effect)
IIb	Randomized controlled trial (with nondefinitive results i.e. a point estimate that suggests a clinically effective effect with confidence interval that overlaps the threshold clinically significant effect)
III	Cohort Studies (Two or more groups are selected on the basis of differences in their exposure to a particular agent and followed up to see how many in each group developed a particular disease or other outcomes)
IV	Case Controlled Studies (Patient with a particular disease or condition are identified and matched with controls, like cohort studies case control studies are generally concerned with the etiology of a disease)
V	Cross Sectional Survey (Data are collected at a single time point but may refer retrospectively to health experiences in the past)
VI	Case Reports
VII	Expert Opinion

Table 1. Level of evidence for each individual publication.

A	Directly based on Category I or IIa evidence and at least one meta analysis
B	Directly based on Category IIb, III or IV or extrapolated from Category I or IIa evidence
C	Directly based on Category V or VI evidence or extrapolated from Category I, II, III or IV
*	Good practice point, recommended best practice based upon clinical experience of the guideline development group

Table 2. Grades of recommendation.

Author, year	Design	Subjects	Treatment	n	Intensity/Duration	Outcomes/Follow-up	Results	Comments
Sonde et al., 1998, ¹³ 2000 ¹⁴ [IIb]	Non-blinded RCT ^a	Chronic stroke survivors (> 6 mo); UE ^b paresis	1. NMES ^c to wrist/ elbow extensors & deltoids + PT ^d 2. PT alone	26 18	Both groups: PT twice/ week. Group 1: NMES 60 min/d, 5 days/ wk, 3 mo.	Fugl-Meyer, Modified Ashworth Scale & Barthel Index at post-treatment (1998) and 3-yrs post-treatment (2000).	NMES group exhibited significant improvements in Fugl-Meyer score at end of treatment (p = 0.013), but not at follow-up. No effect on Ashworth Scale or Barthel Index.	Uncertain randomization outcome; unequal treatment intensity; short-term benefit may be due to increased treatment intensity or NMES; evaluation bias and placebo effect cannot be ruled out.
Chae et al., 1998 ¹⁵ [IIb]	Double-blinded RCT	≤ 4 wks from stroke; UE paresis; finger extension ≤ 3/5 (MRC ^e)	1. NMES to wrist and finger extensors 2. Placebo	14 14	60 min/d, 5 d/wk, 3 wks.	Fugl-Meyer & FIM ^f at post-treatment & at 4 and 12 wks post-treatment.	Significant improvement in Fugl-Meyer scores at post-treatment (p = 0.05), 4 wks (p = 0.05) and 12 wks (p = 0.06). No effect on FIM.	Modest follow-up; high selective drop-out rate; uncertain randomization; benefit of NMES may be due to selection bias or NMES.
Powell et al., 1999 ¹⁶ [IIb]	Single-blinded RCT	2-4 wks from stroke; UE paresis; wrist extension ≤ 4/5 (MRC)	1. NMES + PT 2. PT alone	30 30	Both groups: "Standard" inpatient rehabilitation. Group 1: NMES 1.5 hrs/d, 8 wks.	Wrist extension torque, ARAT, ^g Barthel Index, 32 weeks follow-up	NMES group exhibited improved wrist extension torque at 8 (p=0.004) and 32 (p= 0.014) wks, and improved ARAT at 8 wks (p=0.11). No effect on Barthel Index.	Good long-term follow-up; comparable baseline; unequal treatment intensity; benefit may be due to greater treatment intensity or NMES; placebo effect cannot be ruled out.
Wong et al., 1999 ¹⁷ [IIb]	Non-blinded RCT	10-14 d from stroke	1. EA ^h 4 UE acupuncture points + PT/OT 2. PT/OT alone	59 59	Both groups: PT/OT >2h/d. Group 1: EA 30 min/da, 5d/wk, 2 wks.	Brunnstrom's stages and FIM at post-treatment	NMES group exhibited improved Brunnstrom's stages (p=0.009) and FIM (p=0.04).	No follow-up; unequal treatment intensity; benefit may be due to greater treatment intensity or EA; evaluation bias and placebo effect cannot be ruled out.

*RCT: Randomized clinical trial ^b UE: Upper extremity ^c NMES: Neuromuscular electrical stimulation	^d PT: Physical therapy ^e MRC: Medical research council ^f FIM: Functional Independence Measure	^g ARAT: Action Research Arm Test ^h EA: Electroacupuncture (surface electrical stimulation at acupuncture sites to produce muscle contraction)
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Table 3. Effectiveness of cyclic neuromuscular electrical stimulation for motor relearning. The level of evidence for each study is in brackets.

Author, year	Design	Subjects	Treatment	n	Intensity/ Duration	Outcomes/ Follow-up	Results	Comments
Bowman et al., 1979 ²⁰ [IIb]	Non-blinded RCT	3 wks to 4 mo; UE ^b paresis; 5-30° active wrist ex-tension; intact cognition	1. Wrist extension BFB, ^c NMES ^d and PT. ^e 2. PT alone.	15 15	Both groups: PT 5 d/ wk for 4 wks. Group 1 also received NMES and BFB 60 min/d	Wrist extension torque & AROM ^f at end of treatment	BFB/NMES group improved more on both outcome measures (p<0.05).	No follow-up; unequal treatment intensity; unable to assess randomization; treatment effect may be due to greater treatment intensity, BFB, NMES or other confound. Evaluation bias and placebo effect cannot be ruled out.
Kraft et al., 1992 ²³ [IV]	Non-blinded, non-RCT	> 6 mo from stroke; UE paresis; clinically stable	1. EMG triggered NMES 2. Low intensity NMES 3. PNF ^g PT 4. No treatment	6 4 3 5	Group 1: 1 hr/d, 3/wk, 12 wks; Group 2: 30 min/d, 5/wk, 12 wks; Group 3: same as 1; Group 4: no treatment	Fugl-Meyer, grip strength, Jebson Taylor hand function test at end of treatment and at 3, 6 and 9-mo post-treatment	Groups 1, 2, and 3 in aggregate improved more on Fugl-Meyer than control at 3 mo (p < 0.001), 6 mo (P < 0.01) and 9 mo (p = 0.05); no differences between groups	Long-term follow-up; very small sample size; may have been confounded by baseline differences ; cannot determine which of the 3 treatment group is most effective. Evaluation bias and placebo effect cannot be ruled out.
Francisco et al., 1998 ²⁴ [IIb]	Single-blinded RCT	≤ 6 wks from stroke; UE paresis; presence of wrist extension EMG	1. EMG triggered NMES to wrist extensor 2. ROM ^h exercises	4 5	60 min/d, 5 d/wk, for entire inpatient rehabilitation stay.	Fugl-Meyer and FIM ⁱ at discharge	EMG triggered NMES groups exhibited higher Fugl-Meyer (p = 0.05) and FIM (p = 0.02) gain scores.	No follow-up; very small sample size; unable to assess equality of subject characteristics; EMG triggered NMES group had lower baseline motor function, but had longer lengths of stay and received more treatment sessions. Placebo effect cannot be ruled out.
Cauraugh et al., 2000 ²⁵ [IIb]	Non-blinded RCT	>1 yr from stroke; active wrist extension of at least 20 deg from 90 deg flexion; no more than 75% UE motor recovery	1. EMG triggered NMES to wrist and finger extensors 2. Volitionally activated wrist and finger extension exercise	7 5	Two 30 min sessions/d, 3d/wk, for 2 wks.	Box and Block, Motor Assessment Scale, Fugl-Meyer Motor Assessment, reaction time and sustained muscle contraction at end of treatment	EMG triggered group exhibited significant improvements in Box and Block (p<0.05) and sustained muscle contraction (p<0.04), but not in Motor Assessment Scale, Fugl-Meyer or reaction time.	No follow-up, very small sample size; unable to assess equality of subject characteristics; may have been confounded by better baseline motor scores for the treatment group; short-term benefit due to evaluation bias and placebo effect cannot be ruled out.
Cauraugh and Kim, 2002 ²⁶ [IIb]	Non-blinded RCT	>1 yr from stroke; active wrist or finger extension of at least 10 deg from 90 deg flexion; no more than 80% UE motor recovery	1. Unilateral EMG triggered NMES to wrist and finger extensors 2. EMG triggered NMES coupled with simultaneous active wrist and finger extension of the unimpaired limb. 3. Voluntary wrist and finger extension of the impaired limb only	10 10 5	Three 30 min sessions/d, 2d/wk, for 2 wks	Box and Block, reaction time and sustained muscle contraction at end of treatment	Group 1 exhibited improved Box and Block test, pre-motor reaction time and sustained muscle contraction over Groups 2 and 3. Groups 1 and 2 exhibited improved motor reaction time over Group 1. Group 2 exhibited improved Box and Block test over Group 3.	No follow-up, very small sample size; may have been confounded by difference in baseline between groups; short-term benefit due to evaluation bias and placebo effect cannot be ruled out.

*RCT: Randomized clinical trial	^d NMES: Neuromuscular electrical stimulation	ⁱ FIM: Functional Independence Measure
^b UE: Upper extremity	^e PT: Physical therapy	gPNF: Proprioceptive neuromuscular stimulation
^c BFB: Biofeedback	^f AROM: Active range of motion	^h ROM: Range of motion

Table 4. Effectiveness of biofeedback and EMG triggered neuromuscular electrical stimulation for motor relearning. The level of evidence for each study is in brackets.

Author, year	Design	Subjects	Treatment	n	Intensity/ Duration	Outcomes/ Follow-up	Results	Comments
Baker & Parker, 1986 ⁶⁰ [IIb]	Single-blinded RCT (Treatment)	≥ 5 mm subluxation; 3-37 wks from stroke; no pain criteria.	1. NMES ^b 2. Hemisling/ arm support	31 32	Group 1: 6-7 hrs of NMES/ day, 6 weeks.	Degree of subluxation (all subjects) and pain (limited sample) at end of treatment	NMES group exhibited significant improvement in subluxation, but not in pain	No follow-up; comparable baseline; short-term benefit in subluxation; inadequate pain assessment; placebo effect cannot be ruled out.
Leandri et al., 1990 ³⁹ [IIb]	Double-blinded RCT (Treatment)	Subacute ^c ischemic stroke survivors	1. High intensity TENS ^d (motor activation) 2. Low intensity TENS (sensory threshold) 3. Placebo	20 20 20	TENS/placebo treatment 3x/wk for 4 wks plus daily "basic physical treatment"	Range of motion: Abduction, forward flexion, extension, external rotation at end of treatment and at 1 month post-treatment.	Group 1 demonstrated significant improvement in ROM. Group 2 demonstrated modest improvement. Group 3 exhibited no improvement	Short-term follow-up; comparable baseline; treatment dose not provided; unclear whether outcome refers to pain-free ROM or absolute ROM; superiority of group 1 based on in-group analysis only.
Faghri et al., 1994 ⁶³ [IIb]	Non-blinded RCT (treatment/prevention)	< 4 wks from stroke; shoulder flaccid/paralysis; no pain criteria.	1. NMES + PT ^e 2. PT alone	13 13	Group 1: 6 hrs NMES/d, 7 d/wk, 6 wks; both groups: PT	Arm function, arm tone, EMG, pain-free ROM ^d & subluxation at end of treatment & 6 wks	NMES group showed improved ROM and subluxation at end of treatment and follow up. NMES group also showed improvements in arm function, EMG activity and spasticity at end of treatment but not at follow-up.	Small sample size; short-term follow-up; comparable baseline; benefit in ROM only via in-group analysis; benefits in EMG, motor function, spasticity not maintained at follow-up; evaluator bias and placebo effect cannot be ruled out.
Chantrain et al., 1999 ⁶¹	Non-blinded alternate assignment (treatment)	2-4 weeks from stroke; subluxed shoulder with pain.	1. NMES + PT 2. PT alone	57 58	Group 1: 2-3 hrs NMES/day, 5 wks; both groups: PT	Shoulder subluxation, resting pain, passive and active pain-free ROM and arm function at 1, 3, 6, 12 & 24-mo post-treatment	NMES group exhibited decreased subluxation and pain and increased arm function.	Large sample; long-term follow-up; unable to assess equivalency of group; evaluation bias and placebo effect cannot be ruled out.
Linn et al., 1999 ⁶² [IIb]	Single-blinded RCT (prevention)	Within 48 hours of stroke; Arm strength < 2/5 (MRC). ^g	1. NMES + PT/OT ^f 2. PT/OT only	20 20	Group 1: 2-4 hours/day, 4 wks; both groups: PT/OT;	Subluxation, pain-free ROM, arm function at the end of treatment and at 8 wks post-treatment	NMES group exhibited a trend toward decreased subluxation at 4 wks, but not at 8 wks.	Short-term follow-up; comparable baseline; transient benefit in subluxation, but no effect on pain; evaluation bias and placebo effect cannot be ruled out.
Kobayashi et al., 1999 ⁴³ [IIb]	Non-blinded RCT (treatment)	Chronic stroke survivors (mean > 1yr from stroke) with subluxation under downward stress (traction).	1. NMES of supraspinatus + PT 2. NMES of middle deltoid + PT 3. PT alone	6 6 5	Groups 1 and 2: Graduated duration and intensity of NMES, 2 sessions/d, 5d/wk, 6 wks; All groups: PT	Subluxation with and without stress, maximal voluntary abduction force, EMG of supraspinatus and deltoid under isometric conditions, pain and muscle tone of pectoralis major and MRI of rotator cuff at end of treatment.	NMES groups exhibited improvements in subluxation under stress, abduction force and EMG strength; no change in muscle tone.	Small sample size; no follow-up; unequal groups; improvements in abduction force and EMG amplitude based only on within-group analysis; >50% missing data for pain and MRI data; observed effect may be due to difference in intensity, evaluation bias, placebo effect or unequal groups.
Wang et al., 2000, ⁴⁵ 2002 ⁴⁶ [IIb]	Non-blinded RCT (treatment)	Acute stroke survivors (<21 d from stroke) with shoulder subluxation; no pain criterion	1. NMES 2. No NMES	8 8	Group 1: NMES 6hr/d, 6 wks; Group 2: no details provided.	Subluxation, pain-free ROM and Fugl-Meyer at end of treatment and at 6-wks post-treatment	NMES group exhibited improvement in subluxation (within-group analysis) and Fugl-Meyer (across groups), but no improvement in pain-free ROM.	Small sample size; short-term follow-up; no details provided on nature of control group; comparable baseline; improvement in subluxation only based on within-group analysis; evaluation bias and placebo effect cannot be ruled out.
Wang et al., 2000, ⁴⁵ 2002 ⁴⁶ [IIb]	Non-blinded RCT (treatment)	Chronic stroke survivors (>1 yr from stroke) with shoulder subluxation; no pain criterion	1. NMES 2. No NMES	8 8	Group 1: NMES 6hr/d, 6 wks; Group 2: no details provided	Subluxation, pain-free ROM and Fugl-Meyer at end of treatment and at 6-wks post-treatment	No improvement in subluxation, Fugl-Meyer or pain-free ROM.	Small sample size; short-term follow-up; no details provided on nature of control group; comparable baseline; no therapeutic benefit.

^a RCT: Randomized clinical trial ^b NMES: Neuromuscular electrical stimulation ^c Time from stroke not specified in inclusion criteria; mean approximately 3-mo post stroke	^d TENS: Transcutaneous electrical nerve stimulation ^e PT: Physical therapy ^f ROM: Range of motion	^g MRC: Medical Research Council ^h OT: Occupational therapy
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Table 5. Effectiveness of cyclic neuromuscular electrical stimulation for shoulder subluxation and pain. The level of evidence for each study is in brackets.

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ORTHOPAEDIC MANAGEMENT OF UPPER EXTREMITY DYSFUNCTION FOLLOWING STROKE (R13)

Mary Ann E. Keenan, MD

ORTHOPAEDIC SURGERY AS A REHABILITATION TOOL

The effects of injury to the brain extend beyond the confines of the skull and the subsequent cognitive function of the brain. The musculoskeletal system is profoundly affected by brain dysfunction. Hypertonicity, the unmasking of primitive reflexes, and impaired motor control all contribute to the abnormal limb positions, contractures, and impaired mobility so frequently encountered in persons with brain injury.

The converse is also true. The brain is strongly affected by dysfunction of the musculoskeletal system. Just as the shoulder and elbow position the hand for grasping and manipulating objects, the musculoskeletal system gives mobility to the brain and positions it to interact with the world. Mobility of the individual is a key element of human life and of fundamental importance to our well being.

Professionals working in the field of brain injury and stroke rehabilitation are knowledgeable about the cognitive and behavioral deficits that accompany brain injury. It has been our experience that less importance has been given to the musculoskeletal impairment that results from brain trauma or stroke. The penalties of musculoskeletal limitations for the individual can be devastating. Improving an individual's physical mobility is often therapeutic leading to increases in their cognitive, behavioral and emotional capacities.

Wellness promotion has become an objective of medical care. This cannot mean the complete prevention of disease, injury and disability. In the physically disabled population, wellness promotion means maximizing function and mobility in order to avoid the complications of their chronic incapacity. Potential complications of physical immobility include decubiti, infection, pain, social isolation, physical and emotional dependence. For society this results in a costly loss of productivity for the patient and often family members as well.

EXPECTATIONS AND TIMING OF ORTHOPAEDIC SURGERY

When evaluating patients with central nervous system dysfunction, questions commonly arise regarding the indications for surgery, the cost, what outcome to expect, and the practicality of this approach. These issues should be considered on an individual basis for each patient. General principles have been delineated which can serve as guidelines for decision making.

1. Operate early - before deformities are severe and fixed.

Orthopaedic surgery is a powerful rehabilitation tool. It is often the only treatment that will correct a limb deformity or improve function. Surgery should not be considered a

treatment of last resort when "conservative" measures have failed. Physical and occupational therapy cannot effect a permanent change in motor control. Drug therapy for increased muscle tone has generalized effects and cannot be targeted to specific offending muscles. Phenol blocks and botulinum toxin injections provide only temporary modulation of muscle tone. When a permanent treatment is needed to decrease muscle tone or redirect a muscle force, surgery should be considered. The results of surgical intervention are improved when deformities are corrected early. Less muscle lengthening is needed when deformities are mild and there is little or no fixed contracture to overcome. Early surgery preserves maximum muscle strength, joint capsule and ligament flexibility, and articular cartilage integrity. In general, the patient will also be in better physiologic condition to undergo surgery if there has not been a period of several years of immobility.

2. Better underlying motor control means better function for the extremity.

Orthopaedic surgery cannot impart control to a muscle. Lengthening a spastic muscle can improve its function by diminishing the overactive stretch response and uncovering any control that was present. Successful surgery depends on a careful evaluation preoperatively to determine the amount of volitional control present in each individual muscle that is affecting limb posture and movement.

Motor performance is a continuous scale with the disabled at the lower end and the elite athlete at the upper end. Infinitesimal improvements in the performance of elite athletes distinguish between the winner and loser. Incremental changes in limb function also result in performance improvements for the disabled individual. Surgery should not be reserved for patients with severe impairment and deformity. Individuals with milder degrees of impairment can benefit greatly from relatively simple procedures such as lengthening of the extrinsic finger flexors to regain sufficient fine motor control to perform more intricate hand functions. The amount of improvement correlates best with the degree of underlying motor control and not the severity of the deformity

3. Distinguish between the function of the extremity and the function of the individual.

We commonly speak of "functional" and "non-functional" surgical procedures. These terms refer to the expected outcomes for a limb but do not indicate the outcome for the person as a whole. Surgical releases of an arm contracted in a flexed and internally rotated position in a hemiplegic patient often allows the person to become independent in dressing even though the arm itself remains non-functional.

4. Consider the cost of not correcting limb deformities.

The cost of motor control evaluation using dynamic electromyography (EMG) is relatively modest for the benefits it provides. Dynamic EMG is a one time expense. The cost of performing an incorrect surgical procedure that fails to correct or worsens a limb deformity is much greater. The cost of performing a surgical procedure is likewise limited when compared to a lifetime of attendant care, spasticity medications, repeated blocks, orthotics to control limb position, complications such as skin ulceration and infection, and lost productivity for the patient and caretakers.

ORTHOPAEDIC MANAGEMENT OF STROKE

The Period of Acute Injury

The orthopaedic surgeon is rarely involved in the acute care of the stroke patient. Efforts at this time are directed towards the medical stabilization of the patient. In some cases the orthopaedic surgeon may be asked to assist with splinting extremities to prevent limb deformities.

The Period of Physiologic Recovery

Spontaneous neurologic recovery occurs primarily during the first six months following a stroke. During the subacute phase limb flaccidity is changing to spasticity. The patient is commonly in a rehabilitation facility for a portion of this time. Muscle weakness can result in joint subluxation or ligamentous laxity if the limb is not protected using a sling to support the shoulder or splints to support the wrist. When spasticity becomes pronounced, temporary measures must be used to prevent contracture formation until spontaneous neurologic recovery has ceased.

The Period of Functional Adaptation to Residual Deficits

After six months the patient is usually neurologically stable. Definitive decisions can then be made regarding bracing or surgery to correct limb deformities and rebalance the muscle forces. This is the time of greatest contribution by the orthopaedic surgeon.

Question #1

What is the general evidence that supports the surgical treatment of upper extremity dysfunction and deformity in stroke?

Aldwell CB, Wilson DJ, Braun RM. Evaluation and treatment of the upper extremity in the hemiplegic stroke patient. *Clin Orthop.* 1969 Mar-Apr;63:69-93.

Level V: Expert opinion. Review article describing surgical treatment techniques.

Lusskin R, Grynbaum BB, Dhir RS. Rehabilitation surgery in adult spastic hemiplegia. *Clin Orthop.* 1969 Mar-Apr; 63:132-41.

Level V: Expert opinion. Review article describing surgical treatment techniques.

Waters R, Rhoades M, Montgomery J. Improvement of physical function after stroke: surgical and orthotic management. *J Am Geriatr Soc.* 1975 Jun;23(6):248-53.

Level V: Expert opinion. Review article describing orthotic and surgical treatment techniques.

Waters RL. Upper extremity surgery in stroke patients. *Clin Orthop.* 1978 Mar-Apr;(131):30-7.

Level V: Expert opinion. Review article describing surgical treatment techniques.

Treanor WJ. Improvement of function in hemiplegia after orthopaedic surgery. *Scand J Rehabil Med.* 1981;13(4):123-35.

Level IV Review article based on case series of 1855 patients over a 25 year period. Successful results reported.

Roper BA. Rehabilitation after a stroke. *J Bone Joint Surg Br.* 1982;64(2):156-63.

Level V Expert opinion. Review article of techniques.

Pinzur, M. S. Surgery to achieve dynamic motor balance in adult acquired spastic hemiplegia: a preliminary report. *J Hand Surg [Am]* 1985;10(4):547-53

Level IV: Case series.

Reconstructive surgery of the upper limb was performed in an attempt to restore dynamic motor balance in 55 patients with adult-acquired spastic hemiplegia. An eight-level grading system was developed to determine the level of functional capacity. Because this system proved useful in predicting the results of surgery, it was utilized for operative planning. A two-level increase in functional grade was necessary for patients to obtain a meaningful increase in function. The average improvement after surgery was 2.10 functional levels. A two-level increase was achieved in 73.2% of the patients. No patient decreased in grade, and only one remained unchanged. In selected patients with upper limb spasticity, a predictable improvement in functional capacity can be obtained with dynamic motor balancing surgery.

Level IV Case series

Swanson AB, de Groot Swanson G. Evaluation and treatment of the upper extremity in the stroke patient. *Hand Clin.* 1989 Feb;5(1):75-96

Level V Expert opinion. Review article of techniques.

Keenan MA. Management of the spastic upper extremity in the neurologically impaired adult. *Clin Orthop.* 1988 Aug;(233):116-25.

Level V Expert opinion. Review article of techniques.

Gardner MJ, Ong BC, Liporace F, Koval KJ. Orthopedic issues after cerebrovascular accident. Am J Orthop. 2002 Oct;31(10):559-68. LEVEL V EXPERT OPINION. REVIEW ARTICLE OF TECHNIQUES.

ASSESSMENT:

- More evidence is needed to scientifically support the general effectiveness of using orthopaedic surgery to treat upper or lower extremity dysfunction or deformities in stroke.
- There is no accepted classification system for describing the wide array of deformities and dysfunction seen in the upper extremity of patients with spasticity from stroke or other central nervous system disorders. This makes comparison of treatments extremely difficult. A priority should be to establish a classification system for limb deformities and dysfunction in persons with upper motor neuron disorders.

Question #2

Current publications treat upper motor neuron syndromes as a group and do not single out those caused by stroke. Is it acceptable to review studies with mixed populations of patients with acquired upper motor neuron syndromes from central nervous system injury such as stroke and traumatic brain injury?

Waters, R. L., Frazier, J., Garland, D. E., Jordan, C., Perry, J. Electromyographic gait analysis before and after operative treatment for hemiplegic equinus and equinovarus deformity. 1982; J Bone Joint Surg [Am] 64; 284-8.

Level I

Prospective study of 27 hemiplegic stroke patients who underwent surgical correction of an equinovarus foot deformity. Surgical plan was based on dynamic EMG/Gait study done with a standardized protocol. All patients had post-operative gait study showing no change in the pattern of dynamic EMG activity.

Keenan MA, Creighton J, Garland DE, Moore T. Surgical correction of spastic equinovarus deformity in the adult head trauma patient. Foot Ankle. 1984;5(1):35-41.

Level III

Retrospective review of 59 consecutive traumatic brain injury patients who underwent surgical correction of an equinovarus foot deformity. Surgical plan based on dynamic EMG/Gait study done with a standardized protocol. Results compared with previous study of stroke patients. No difference seen in patterns of muscle activity between stroke and brain injured patients and same success rate for surgical outcomes.

Keenan MA, Abrams RA, Garland DE, Waters RL.

Results of fractional lengthening of the finger flexors in adults with upper extremity spasticity. J Hand Surg [Am]. 1987 Jul;12(4):575-81.

Level IV

This was a retrospective review of 27 consecutive patients who underwent lengthening of the extrinsic finger flexors to correct a clenched fist deformity. Six patients had a stroke. No differences seen in the clinical appearance or function of the hands before surgery and no differences seen in the results of surgery.

Keenan MA, Fuller DA, Whyte J, Mayer N, Esquenazi A, Fidler-Sheppard R. The influence of dynamic polyelectromyography in formulating a surgical plan in treatment of spastic elbow flexion deformity. Arch Phys Med Rehabil. 2003 Feb;84(2):291-6.

Level I:

This was a prospective study of 21 consecutive patients (22 elbows) with the diagnosis of upper motor neuron syndrome who had an elbow flexion deformity. All patients were evaluated clinically by two surgeons independently of each other and a treatment plan recorded. The patients then underwent laboratory evaluation with dynamic electromyography by an independent examiner using a standardized protocol. The patients were re-evaluated by the surgeons with the results of the laboratory testing and a new treatment plan was recorded. No differences were seen between the patterns of muscle activity between the stroke, traumatic brain injury and adult cerebral palsy patients. The laboratory assessment altered the surgical plan 57 % of the time and was deemed to be very important in planning treatment.

Fuller DA, Keenan MA, Esquenazi A, Whyte J, Mayer NH, and Fidler-Sheppard R. The impact of instrumented gait analysis on surgical planning: Treatment of spastic equinovarus deformity of the foot and ankle. Foot Ankle Int 2002; 23(8) 738-743.

Level I:

Prospective study of 37 consecutive patients (41 feet) with spastic equinovarus foot deformities from upper motor neuron syndromes. All patients were evaluated clinically by two surgeons independently of each other and a treatment plan recorded. The patients then underwent laboratory gait evaluation with dynamic electromyography by an independent examiner using a standardized protocol. The patients were re-evaluated by the surgeons with the results of the laboratory testing and a new treatment plan was recorded. No differences were seen between the patterns of muscle activity between the stroke, traumatic brain injury and adult cerebral palsy patients. The laboratory assessment altered the surgical plan 57 % of the time and was deemed to be very important in planning treatment. Comparison of the

surgical outcomes was made with historical published studies in which the treatment decision was based on clinical assessment alone. Surgical outcomes were superior in the patients whose treatment plan was based on the gait study with dynamic poly-electromyography.

ASSESSMENT:

- It is an acceptable practice to combine stroke and traumatic brain injured patient groups in research regarding the outcomes of surgical treatment of extremity deformities.
- Although it is common clinical practice to employ the same techniques of assessment and treatment for all patients with upper limb spasticity, there is no evidence to support including patients with childhood onset (cerebral palsy) of upper motor neuron disorders when evaluating treatments for stroke patients.

Question #3

What is the evidence supporting the surgical treatment of shoulder subluxation, contracture or dysfunction?

Braun RM, West F, Mooney V, Nickel VL, Roper B, Caldwell C. Surgical treatment of the painful shoulder contracture in the stroke patient. *J Bone Joint Surg Am.* 1971 Oct;53(7):1307-12.

Level IV Case series

Braun RM and Botte MJ. Treatment of shoulder deformity in acquired spasticity. *Clin. Orthop.* 1999;368,54-65.

Level V: Expert opinion. Review article describing surgical treatment techniques.

Keenan MAE and Mehta S. Neuro-orthopaedic management of shoulder deformity and dysfunction in brain injured patients. *J. Head Trauma Rehabil.* 2004;19(2), 143-154.

Level IV:

- Consecutive case series of 10 shoulders in 8 patients with stroke or brain injury who had successful surgical release of shoulder adduction and internal rotation contractures. The resting position and passive range of motion improved significantly after surgery in all ten shoulders. There were no complications of surgery. All patients had failed non-surgical treatment.
- Also included in this paper was a consecutive case series of 17 shoulders in 17 patients who had selective lengthening of dyssynergic internal rotator and extensor muscles. The offending muscles were identified prior to surgery using multi-channel dynamic EMG and functional improvement was demonstrated using a temporary local anesthetic block of the offending muscles in the laboratory. There was a statistically significant improvement in active motion in all three planes. Active shoulder flexion increased an average of 46 degrees. Active external rotation increased a mean of 28 degrees

and abduction improved 29 degrees. There were no complications of surgery and all patients were satisfied with the outcome.

- Also included in this paper was a consecutive case series of 11 shoulders in 11 patients who a biceps suspension procedure performed for painful inferior subluxation of the shoulder. All 11 patients had had at least 2 year follow-up. There was a mild recurrence of the inferior subluxation in 2 patients and moderate recurrence in one patient as measured on radiographs of the shoulder while standing or sitting with the arm unsupported. Pain was resolved in all 11 patients.

Pinzur MS, Hopkins GE. Biceps tenodesis for painful inferior subluxation of the shoulder in adult acquired hemiplegia. *Clin Orthop.* 1986 May;(206):100-3.

Level IV Case series of six patients.

Painless inferior subluxation of the shoulder is a common finding following stroke and is a manifestation of the dynamic nature of the disorder. The weight of the limb is not counterbalanced by shoulder musculature. This is a preliminary report of a simple tenodesis procedure performed in six patients with uniformly successful reduction of the subluxation. The tenodesis is performed through a short deltopectoral approach. The tendon of the long head of the biceps is looped over the coracoid process of the scapula and secured with a barbed staple, thus reducing the subluxation. The indications were painful inferior subluxation of a flail shoulder and failure of multiple orthotic attempts to relieve discomfort. Follow-up evaluation ranged from ten to 42 months with no instances of pain or recurrent subluxation in five cases. The one failure was in a patient whose pain was thought to be thalamic in origin. The subluxation was reduced, but the pain persisted.

ASSESSMENT:

- Release of adduction, internal rotation shoulder contractures causing problems of passive function in patients who lack active movement of the arm following a stroke is supported by the literature. Additional prospective studies would provide more firm support of this clinical practice.
- A single study of selective lengthening of dyssynergic internal rotator and extensor muscles of the shoulder to improve the active function of the arm provides preliminary support for this procedure. A more detailed prospective study is needed.
- Two cases series treating inferior subluxation of the shoulder were reviewed. The first was a study using a distally based tenodesis of the biceps tendon to reduce painful inferior subluxation of the glenohumeral joint. The second series used a proximally based technique using the biceps tendon to create a suspensory ligament. Both series were preliminary

and showed a modest level of success. Additional studies are needed before this treatment can be recommended.

Question #4

What is the evidence supporting the surgical treatment of spastic elbow contracture or dysfunction?

Garland DE, Thompson R, Waters RL. Musculocutaneous neurectomy for spastic elbow flexion in non-functional upper extremities in adults. *J Bone Joint Surg Am.* 1980 Jan;62(1):108-12.

Level IV: Case Series

The charts of twenty-nine patients who had undergone thirty musculocutaneous neurectomies for acquired spasticity of the elbow in a non-functional upper extremity were reviewed. The most common causes of the spasticity were cerebrovascular accident (59 per cent) and head injury (24 per cent). The aims of the operation were to increase the patient's capacity for self-care and to improve ambulation, personal hygiene, and appearance. Patients who had 30-degree flexion contractures preoperatively did not require a cast postoperatively; those who had 30 to 75-degree flexion contractures preoperatively required a cast postoperatively; and patients who had flexion contractures of more than 75 degrees preoperatively required a concomitant release of soft tissue in the elbow and application of a cast postoperatively. One patient who was operated on to improve appearance had no active elbow flexion postoperatively and was regarded as having a poor result. Musculocutaneous neurectomy is a safe, reliable procedure for treating the spastic elbow in the non-functional upper extremity.

Garland DE, Lucie RS, Waters RL. Current uses of open phenol nerve block for adult acquired spasticity. *Clin Orthop.* 1982 May;(165):217-22.

Level IV: Case series

Forty-nine open phenol nerve injections were performed for acquired spasticity during a five-year period. The most common etiology of acquired spasticity was closed head injury (70%). Thirteen phenol injections to the musculocutaneous nerve were performed for excessive elbow flexion. The immediate results were absence of biceps and brachialis muscle activity, and an average gain of 43 degrees in extension. The effects of the nerve block subsided within six months. Nine nerve blocks were followed for more than one year. In two patients the upper extremities were almost normal. In the remaining seven the upper extremities were nonfunctional. Twenty-eight phenol injections to the posterior tibial nerve were performed for uncontrolled excessive plantar flexion and/or fixed equinus. The immediate result was cessation of gastrocnemius and soleus activity. Twenty-seven ankles attained a neutral position. The effects of the nerve block subsided within six months. Thirteen patients with 19 blocks were followed for more than eight months. Nine

patients underwent lengthening of the Achilles tendon and six patients required orthotic devices for control of plantar flexion spasticity. In general, patients with acquired spasticity who require open phenol nerve blocks are unlikely to have normal functioning extremities when the effects of the nerve block have subsided.

Keenan, M.A.E., Kauffman, D.L., Garland, D.E. and Smith C.: Late ulnar neuropathy in the brain-injured adult. *J. Hand Surg.* 13A:120-124, 1988.

Level IV: Case Series

Twenty-five brain-injured adults who were treated for tardy ulnar neuropathy during a 5-year period were studied. Two patients had bilateral involvement. The incidence of late ulnar neuropathy in this population was determined to be 2.5%. The ulnar neuropathy was always on the neurologically impaired side and associated with significant spasticity. Diagnosis was made when intrinsic atrophy was noted in the hand. No patient initiated a subjective complaint. Nerve conduction velocity measurements confirmed impingement of the ulnar nerve in the cubital canal in 16 cases. Twenty-one of the 27 (78%) elbows had moderate to severe heterotopic ossification causing impingement of the ulnar nerve. All patients were treated by anterior transposition of the ulnar nerve. Follow-up averaged 22.7 months. Twenty-three (85%) extremities had complete recovery of ulnar nerve function. Four patients had improved but incomplete recovery of function. Prolonged compression of the nerve led to incomplete recovery

Keenan, M.A.E. and Perry, J.: Evaluation of upper extremity motor control in spastic brain-injured patients using dynamic electromyography. *J. Head Trauma Rehabil.* 5(4):13-22, 1990.

Level V: Expert opinion. Review paper with multiple clinical examples.

Keenan, M.A.E.; Haider, T. and Stone, L.R.: Dynamic electromyography to assess elbow spasticity. *J Hand Surg.* 15A:607-614, 1990.

Level I: Prospective evaluation of elbow motor control in 45 elbows of 43 consecutive patients with upper motor neuron syndrome from CNS injury.

Control of elbow motion was evaluated in 45 extremities of adults with spasticity resulting from traumatic brain injury with use of dynamic electromyography. Simultaneous recording of elbow motion was obtained using a double parallelogram goniometer. Thirty-four male and 9 female patients were studied. Mean elbow flexion was 85 degrees and mean extension was 20 degrees. The average time of elbow flexion was 1.8 seconds. Extension time was prolonged to a mean of 4.0 seconds. Dynamic electromyography revealed a consistent pattern of muscle activity. Severe spasticity was noted in the brachioradialis muscle. Moderate spasticity was present in the biceps and only mild spasticity was seen in the brachialis muscle. Normal phasic muscle activity was the rule in the triceps. All patients

had active elbow flexion, but the flexor spasticity limited smooth extension. Elbow flexor spasticity, especially of the brachioradialis and biceps muscles, commonly interferes with hand placement. Lengthening of the biceps and brachialis tendons combined with release of the brachioradialis enhances elbow motion and improves hand placement.

Keenan, M.A.; Ahearn R.; Lazarus, M; and Perry, J.: Selective release of spastic elbow flexors in the patient with brain injury. *J. Head Trauma Rehabil* 11:57-68, 1996.

Level II: Prospective study.

This was a prospective study of 21 consecutive patients who underwent selective surgical lengthening of the elbow flexor muscles. Mean follow-up was 29 months (range 24-50 months). Motor control, velocity of movement, and elbow range of motion were documented before and after surgery using dynamic electromyography, video and electrogoniometry. All patients showed improved motion after surgery. The mean arc of elbow motion was 62 degrees prior to surgery and 111 degrees postoperatively. The time required for elbow flexion improved from 2.9 seconds to 1.7 seconds. Elbow extension time improved from 4.8 seconds to 2.2 seconds after surgery with smoothing of the extension pattern on electrogoniometry. The improved elbow motion resulted in improved upper extremity function in 20 of the 21 patients.

Keenan MA, Fuller DA, Whyte J, Mayer N, Esquenazi A, Fidler-Sheppard R. The influence of dynamic polyelectromyography in formulating a surgical plan in treatment of spastic elbow flexion deformity. *Arch Phys Med Rehabil.* 2003 Feb;84(2):291-6.

Level I:

This was a prospective study of 21 consecutive patients (22 elbows) with the diagnosis of upper motor neuron syndrome who had an elbow flexion deformity. All patients were evaluated clinically by two surgeons independently of each other and a treatment plan recorded. The patients then underwent laboratory evaluation with dynamic electromyography by an independent examiner using a standardized protocol. The patients were re-evaluated by the surgeons with the results of the laboratory testing and a new treatment plan was recorded. No differences were seen between the patterns of muscle activity between the stroke, traumatic brain injury and adult cerebral palsy patients. The laboratory assessment altered the surgical plan 57 % of the time and was deemed to be very important in planning treatment.

Pinzur MS, Sherman RS, Dimonte-Levine P. Triceps spasticity in traumatic hemiplegia: diagnosis and treatment. *Arch Phys Med Rehabil.* 1987 Jul;68(7):446-9.

Level IV: Case series

Three patients with adult-acquired hemiplegia are de-

scribed with the unusual dynamic deformity of spasticity of the triceps muscle. This deformity produces motor imbalance with the triceps overpowering the elbow flexors, thus impeding volitional elbow flexion. The nature of the deformity was defined by electromyography of the muscle groups about the elbow, which demonstrated out-of-phase inhibitory electrical activity of the triceps muscle. Treatment consisted of V-Y lengthening of the triceps muscle to achieve agonist-antagonist motor balance. The operation improved hand placement for all three patients.

ASSESSMENT

- Surgical phenol blocks of the ulnar nerve are effective in decreasing elbow flexor spasticity. This procedure is rarely performed as it leads to permanent scarring of the musculocutaneous nerve. Surgical phenol blocks have been replaced by newer techniques such as chemodenervation with botulinum toxin.
- Musculocutaneous neurectomy to denervate the biceps and brachialis muscles can be considered for those elbow flexion deformities which are primarily dynamic in nature and do not have a significant component of fixed contracture. The brachioradialis muscle, however, is a significant contributor to spastic elbow flexion deformities. The brachioradialis is innervated by the radial nerve and will not be affected by musculocutaneous neurectomy.
- Ulnar nerve compression in the cubital canal can result from elbow flexion deformities.
- Selective lengthening of spastic elbow flexors based on dynamic EMG studies is an established and effective technique for correcting deformity and improving function.
- Triceps spasticity is much less common. V-Y lengthening of the triceps muscle has been shown in a small series of cases to help restore balance across the elbow joint. Further study of this deformity and procedure is needed.

Question #5

What is the evidence supporting the surgical treatment of hand and thumb contractures?

Keenan, M.A.E.; Abrams, R.A.; Garland, D.E.; and Waters, R.L.: Results of fractional lengthening of the finger flexors in adults with upper extremity spasticity. *J. Hand Surg.* 12A(4):575-581, 1987

Level IV: Case series collected retrospectively

Flexor spasticity is common in the upper extremity after insult to the central nervous system. This leads to decreased function and hygiene problems as a result of the inability to extend the fingers. The results of fractional lengthening of the finger flexors of 27 patients with upper extremity flexor spasticity of the finger flexors were examined. Patients were divided preoperatively into those with potentially functional hands and those who were nonfunctional based on the presence of motor control and hand sensibility.

Follow-up time averaged 33 months. Postoperatively, all five nonfunctional hands, which lacked any motor control, improved in posture, and the hygiene problems resolved. Twenty of the 22 patients with potentially functional hands (91%) improved their spastic hand function score, a mean of 3.7 points. Two patients (9%) decreased their spastic hand function score as a result of overlengthening of the finger flexors, with loss of grip strength.

Keenan MA, Romanelli RR, Lunsford BR. The use of dynamic electromyography to evaluate motor control in the hands of adults who have spasticity caused by brain injury. *J Bone Joint Surg Am.* 1989 Jan;71(1):120-6

Level I: Prospective study of 48 consecutive hands in 42 patients with upper motor neuron syndrome from CNS injury.

A dynamic electromyographic analysis of grasp and release, performed on forty-eight upper extremities of forty-two adults who had had injury to the brain causing spasticity, showed volitional motor control of the finger flexors in 80 per cent and active extension of the fingers in 60 per cent. The flexor pollicis longus showed volitional control in 75 per cent of the hands and the extensor pollicis longus showed active control in 50 per cent. The extensor carpi radialis longus acted as an appropriate stabilizer of the wrist in 85 per cent of the extremities. Fourteen muscles had out-of-phase activity that could not be detected on clinical examination. The position of the elbow did not appreciably influence the electromyographic pattern of motor control in the hand.

Botte, M.J., Keenan, M.A., Gellman, H., Garland, D.E. and Waters, R.L.: Surgical management of spastic thumb-in-palm deformity in adults with brain injury. *J. Hand Surg.* 14A:174-181, 1989.

Level IV: Case series

Spastic thumb-in-palm deformity was surgically treated in 27 adults with brain injury. Procedures included muscle lengthening, recession, or release, arthrodesis of the thumb interphalangeal joint, or Z-plasty of the thumb web space. At mean follow-up of 39 months, 23 of 27 had a satisfactory correction. Unsatisfactory results included two with inadequate correction and two with over-correction. Surgical treatment of this entity requires careful preoperative planning, addressing predominantly those spastic muscles responsible for the deformity.

Rayan GM, Saccone PG. Treatment of spastic thumb-in-palm deformity: a modified extensor pollicis longus tendon rerouting. *J Hand Surg [Am].* 1996 Sep;21(5):834-9.

Level IV: Case series

Fourteen patients (15 hands) with spastic thumb-in-palm deformities were treated with a modified technique of extensor pollicis longus tendon rerouting. Twelve patients obtained satisfactory correction of their deformities. Although functional improvement was not always anticipated, it was

achieved to some degree in 12 patients. Extensor pollicis longus tendon rerouting can provide satisfactory correction of severe thumb-in-palm deformity especially when combined with other procedures such as metacarpophalangeal joint arthrodesis and thumb intrinsic muscle release. The modified rerouting technique can be done with a single incision and allows easy adjustment of tension.

Keenan, M.A.E.; Todderud, E.P.; Henderson, R.; and Botte, M.J.: Management of intrinsic spasticity in the hand with phenol injection or neurectomy of the motor branch of the ulnar nerve. *J. Hand Surg.* 12A(5):734-739, 1987

Level IV: Case series

Thirty-nine adults with acquired spastic disorders who had 21 phenol injections and 21 neurectomies of the motor branch of the ulnar nerve in Guyon's canal for control of intrinsic spasticity in the hand were reviewed. Follow-up averaged 25.8 months for the patients with phenol blocks and 24.3 months for those who had a neurectomy. Intrinsic spasticity was relieved in all hands postoperatively. After the phenol block, which is a temporizing procedure, 13 hands had return of spasticity in 6 months. Eight hands had little or no return of spasticity and required no further treatment. Neurectomy was performed in predominantly nonfunctional hands with severe hygiene problems and with no potential for further neurologic recovery. Hand function was improved in six hands after phenol block and in one hand after neurectomy. Hygiene was improved in all hands after phenol block and in all except one hand after neurectomy. Two wound infections and one wound dehiscence occurred.

Orcutt, S.A., Howard, M., Keenan, M.A.E., Waters, R.L., Stone, L.R., and Gellman, H.: Carpal tunnel syndrome in patients with spastic wrist flexion deformity. *J. Hand Surg.* 15A:940-944, 1990.

Level I: Prospective study

Ten patients with spastic wrist flexion deformities secondary to traumatic brain injury were evaluated for carpal tunnel syndrome. The angle of wrist flexion deformity averaged 75 degrees (range, 58 to 115 degrees). Nerve conduction studies demonstrated prolonged median motor and/or sensory latencies in all patients. Preoperative wick catheter measurements of carpal tunnel pressures in eight patients averaged 11 mm Hg in the resting position, 21 mm Hg in maximal wrist flexion, and 15 mm Hg in maximal extension. Each patient had carpal tunnel release with simultaneous wrist and finger flexor tendon releases or lengthenings. At surgery nine of the median nerves were constricted at the proximal edge of the transverse carpal ligament. The presence of normal carpal tunnel pressures and impingement of the median nerve at the proximal edge of the transverse carpal ligament indicates that the chronically flexed posture of the wrist resulted in median nerve compression, and this condition may be aggravated by underlying pressure from the spastic finger flexors.

Kozin, S. H. and Keenan, M.A.E.: Using dynamic electro-

myography to guide surgical treatment of the spastic upper extremity. *Clin. Orthop.* 288:109-117, 1993.

Level V: Expert opinion.

Upper extremity deformity after brain injury is frequently complex and dominated by spasticity or contracture. Clinical examination of the limb is often difficult and inaccurate. Dynamic electromyography provides valuable information previously unobtainable. Analysis of this data can facilitate appropriate reconstruction of the deformed limb.

Keenan, M.A.E.; Korchek, J.I.; Botte, M.J.; and Garland, D.E.: Results of transfer of the flexor digitorum superficialis tendons to flexor digitorum profundus tendons in adults with acquired spasticity of the hand. *J. Bone Joint Surg.* 69A:1127-1132, 1987.

Level IV: Case series

Thirty-one patients who had transfer of the flexor digitorum superficialis tendons to the flexor digitorum profundus tendons en masse in thirty-four non-functional spastic hands were examined at an average of fifty months postoperatively. All of the patients had had a clenched-fist deformity preoperatively, with severe hygienic problems of the palmar skin and no active function of the hand. Postoperatively, all of the hands were in an open position, which allowed for good hygiene of the palmar surface. A minor wound infection developed in three patients. Neurectomy of the motor branch of the ulnar nerve distal to the Guyon canal was needed for control of spasticity of the intrinsic muscles in twenty-five hands. An intrinsic-minus deformity did not develop in any of the hands that had neurectomy of the ulnar nerve, although an intrinsic-plus deformity developed in seven of the nine hands that did not have a neurectomy.

Pomerance, J.F. and Keenan, M.A.E.: Correction of severe spastic flexion contractures in the non-functional hand. *J. Hand Surg.*, 21A:828-833, 1996.

Level IV: Case series

The superficialis to profundus transfer has been a time-honored treatment of spasticity in nonfunctional hands, but it does not address the many associated problems. Fourteen patients were treated with 15 procedures (1 bilateral) designed to relieve severe flexion contractures of the hand and wrist over a 3-year period with a single-stage comprehensive surgical correction consisting of superficialis to profundus transfer, wrist flexor release, flexor pollicis longus lengthening, wrist arthrodesis, carpal tunnel release, and ulnar motor branch neurectomy or intrinsic release. For all, nonoperative treatment had failed or there were chronic skin problems. The follow-up period averaged 1 year. In 13 of 15 patients, there was wrist fusion after the index procedure, with 1 patient requiring re-plating and another uniting after prolonged casting. Two patients had a residual claw hand with only partial correction of a thumb-in-palm deformity. All preoperative hygiene problems and infections resolved. The comprehensive protocol allowed correction of severe contractures of the hand and wrist by

a single operation with improved care and appearance of the hand.

Rayan GM, Young BT. Arthrodesis of the spastic wrist. *J Hand Surg [Am]*. 1999 Sep;24(5):944-52.

Level IV: Case series

The clinical and radiographic results of 9 patients (11 wrists) who had wrist arthrodeses for severe spastic flexion contracture were evaluated. The spasticity was due to cerebral palsy, traumatic head injury, and cerebrovascular accident. All wrist deformities were aesthetically unappealing and the patients or their caretakers had difficulty with hygiene or function. The subjective evaluation included overall satisfaction, hand hygiene, wrist deformity, functional improvement, and willingness to have surgery again given the same preoperative circumstances. A standardized hand function questionnaire was used to determine functional improvement following surgery. The objective evaluation included clinical evidence of fusion, skin condition, wrist position, and radiographic assessment. The average age of the patients was 22 years at the time of surgery and the average follow-up period was 32 months. All patients were satisfied with the results of the surgery and hygiene improved in all cases. None had palmar skin maceration or breakdown. All patients or their caretakers rated the overall appearance or wrist and hand deformity as improved and all but one patient would agree to have the surgery over again given the same preoperative circumstances. According to a 17-task hand function questionnaire, 8 of 9 patients (10 wrists) reported improved function after surgery. Face washing, propelling a wheelchair, and picking up both large and small objects were among the most frequently improved functions. Radiographic fusion was present in all cases. The average position of wrist fusion was 15 degrees flexion and the average amount of wrist correction was 85 degrees. Improved appearance, hygiene, and a certain degree of upper extremity function, regardless of cognitive abilities, can be expected following arthrodesis for severe spastic wrist deformity.

Romain M, Benaim C, Allieu Y, Pelissier J, Chammas M. Assessment of hand after brain damage with the aim of functional surgery. *Ann Chir Main Memb Super.* 1999;18(1):28-37.

Level V: Expert opinion

The semiology of the hand after brain damage is really rich. Its clinical evaluation remains quite difficult and must be integrated in the neuro-orthopedic and cognitive context. Deficiency, neuropsychological, analytic and functional status, must be assessed before any surgical decision aiming the improvement of prehension. Neuropsychological evaluation precise the hemispheric specialization: right hemisphere lesions conduct to unilateral spatial neglect while left hemispherical lesions determine language troubles and gesture impairment (apraxia). The analytical evaluation describes motor and sensitive function and assesses

spasticity and pain. Concerning the functional assessment, the Enjalbert's score seems to be the most adapted to the upper limb. The assessment of hand deficiency and its origin is necessary to orientate the surgical decision and includes the Zancolli classification for the fingers and wrist and the House classification for the thumb. These classification used for cerebral palsy seems to be insufficient for all the different situations occurring after brain damage. A new classification is proposed based on 3 parameters: fingers extension, thumb abduction and supination. Surgical decision should be examined only after an adapted rehabilitation program.

ASSESSMENT:

- Dynamic poly-EMG studies have been documented to be very helpful in identifying the muscles responsible for deformity and dysfunction in spastic hands.
- Lengthening of the extrinsic wrist and finger flexor muscles was shown helpful in one case series to improve hand function in those patients who have remaining volitional control of the muscles. Additional studies are needed to further document the functional outcomes of these procedures.
- Stabilization of the wrist by arthrodesis has been shown in one case series to improve hand function. Additional studies are needed to establish the indications and confirm the results.
- Carpal tunnel is a documented complication of

severe wrist flexion deformity.

- Severe wrist and finger flexion contractures in patients without active hand function have been shown in several studies to be reliably corrected by the superficialis to profundus tendon transfer. Concomitant wrist fusion, carpal tunnel release and treatment of intrinsic muscle spasticity are recommended.
- Intrinsic hand deformities in hands without active function can be treated by phenol injection or neurectomy of the motor branches of the ulnar nerve in the hand. Surgical treatment of intrinsic spasticity in hands with active function is not yet established.
- Much has been written about the surgical treatment of the spastic thumb-in-palm deformity in patients with cerebral palsy but there has only been a single case series study of this problem in adults with stroke and brain injury. The proximal slide of the thenar muscles was effective in this one series but additional studies are needed.
- There is no accepted classification system for describing the wide array of deformities and dysfunction seen in the upper extremity of patients with spasticity from stroke or other central nervous system disorders. This makes comparison of treatments extremely difficult. A priority should be to establish a classification system for limb deformities and dysfunction in persons with upper motor neuron disorders.

ORTHOTIC MANAGEMENT OF THE UPPER LIMB (R14)

Nicole M. Parent, CO, OTR

ABSTRACT

After reviewing the literature concerning upper extremity involvement, there appeared to be an abundance of case study and expert opinion style of reporting. Without understating the value of these types of publications, these seemed to reveal a lack of controlled studies with focus on functional improvements as a goal in rehabilitation of the stroke patient with hemiplegic arm. Functional problem identification must include solution development that corresponds to the specific clinical situations. Four key points are discussed in the following review of the literature. (1) Shoulder pain is a common affliction of the hemiplegic arm. The incidence of shoulder subluxation and its relationship to the painful shoulder is reviewed. The use of shoulder supports to address this issue is reviewed with relationship to how shoulder supports affect subluxation and if this can correlate to a decreased incidence of pain. (2) Therapeutic techniques are discussed widely in the literature. However the combination of therapeutic techniques with orthotic management is overlooked. The use of orthoses as an adjunct to therapy is discussed. (3) Treatment of orthopedic conditions is well documented in the literature. The treatments of common orthopedic conditions such as contracture development as well as carpal tunnel syndrome in the hemiplegic patient are reviewed. Specific diagnosis and treatment considerations for this patient population are imperative. (4) The use of technology must continue to be expanded to the rehabilitation process of the hemiplegic patient. The use of experimental orthoses is documented in the literature as case studies and may not be applicable to the scrutiny of randomized, controlled trials. However, case studies and expert opinions need to continue to be published to stimulate idea and product development.

In reviewing the literature concerning upper extremity orthotic management of the upper limb with application to the hemiplegic patient, several factors seem to play a key role in developments and improvements. The development of problems that lead to the need for orthotic management are related to the multifactorial and complex disabilities associated with cerebrovascular accident (CVA) and resultant hemiplegia. With CVA being deemed the leading cause of disability in the United States⁴¹ the need for intervention and initiation of research into new techniques and treatments seems vital. With such a diverse set of clinical presentations and the variety of factors influencing outcome, rehabilitation has taken a primary role in restoring functional independence and recovery of quality of life. With specific regard to stroke patients, the recovery process may involve a wide range of clinical pictures as the patient steadily improves or merely changes their clinical picture. The development of orthoses which are not merely functional at the current time, but also able to adjust and compensate for these changes in clinical pictures, are key to the

patient's success. With this task defined, research and new development of ideas based on solid research techniques and methods become increasingly important. Orthotic management plays a key role in the rehabilitation process with regard to therapeutic positioning, muscular retraining as well as prevention of the development of subsequent functional problems. In the spirit of a true multidisciplinary model, there seems to be room for improvement of techniques and methods to support the overlapping of different rehabilitation specialties and their techniques. Currently rehabilitation is considered diverse in its methods, styles in which it is provided, as well as the specific techniques and interventions used. These factors serve as roadblocks to establishing consistency and breakthroughs in clinical research.¹⁵ There seems to be no debate that orthotic management is a necessary and vital piece of the rehabilitation process of stroke patients. However, despite the widespread use of orthoses, the reliable and reproducible research is lacking in quantity as well as quality. The focus of the research must be centered on developing specific solutions to the existing clinical problems seen in the rehabilitation process. Therefore in reviewing the literature, several areas of clinical problems were identified that can be addressed in reference to their current use of orthotics, shortcomings in orthotic techniques as well as areas in need of orthotics solution development and expansion.

There is inconsistency in the literature on the incidence of shoulder pain in the hemiplegic shoulder. Bender¹ reported that shoulder pain can affect 70% of the stroke population while other statistics document range from 38% - 84%.^{20, 42} A clinical picture of a functional and pain free shoulder will facilitate independence of transfers, improve ability with motor coordination of the hand, allow for improved balance and ultimately facilitate more independence with activities of daily living.⁴² There are many theorized causes of shoulder pain. Well documented literature exists in expert opinion format reviewing the anatomical theories behind the etiology of shoulder pain in the hemiplegic patient. In particular, Hummersheim¹⁸ reviews a number of muscular and mechanical factors and their collective influence on the incidence of shoulder pain in the hemiplegic patient. Hemiplegic shoulder pain is often used to label a variety of problems with a number of possible diagnoses. Kaplan²¹ reinforces the importance of distinguishing the differences between shoulder pain with soft tissue involvement and shoulder pain with subluxation. Although contractures, limited range of motion and spasticity are all possible causes, glenohumeral subluxation seems to be the most researched etiology behind shoulder pain in the hemiplegic patient.

When considering the use of shoulder supports and slings, early detection of shoulder subluxation seems to be key in addressing the problem. Although it is suggested that subluxation of the humeral head does not directly cause

shoulder pain, it may exert traction stress to the soft tissue and therefore result in a painful shoulder.²¹ Early detection of this clinical problem may facilitate success of treatment techniques and improve functional capability.⁴⁷ To consider the use of orthotic devices, slings and supports, to address the clinical problem of shoulder pain, a causal relationship seems to be assumed with reference to the studies and case reports that currently exist. Zorowitz's case control study⁵⁰ reviews four shoulder supports and the effects they have on reducing shoulder subluxation. The implication is that the shoulder subluxation is the source of the pain. The study effectively examines the results radiographically for each support and distinguishes the patient scenario most appropriate for each type of sling. However, the key problem identified was pain that inhibits function in the hemiplegic patient. Too great of an assumption must be made between the incidence of shoulder subluxation treated with shoulder supports and the decrease of pain with causal relationship to increased function. Shoulder supports are examined in a number of articles with the approach of case study reports and expert opinions where lapboards, cuff-type slings and arm trough supports were reviewed and defined.⁴ Spaulding³⁸ also presented a biomechanical analysis of supports used for shoulder subluxation defining the biomechanical and design rationale of a variety of shoulder supports. Morin²⁹ produced a cross sectional survey of a technique used involving strapping in addition to a sling to reduce the incidence of shoulder subluxation. Radiographic based results were produced. Zorowitz⁵⁰ performed a case control study on shoulder supports to reduce shoulder subluxation however concluded that although the various supports can reduce shoulder subluxation, there was no determination of ability to correlate the incidence of shoulder subluxation and shoulder pain. Since shoulder pain seems to be the functional limiting component, this area needs additional research with results and determination of success based on functional outcomes and/or correlation between functional improvements and radiographic improvements in position.

There is no contention that there exists a number of effective therapy treatment techniques that are widely applied to the hemiplegic population. These therapeutic treatment techniques are most often applied to the sub-acute population of patients as it has been shown that treatment of chronic patients is less effective.⁴¹ There is also relevant literature discussed previously to support the effectiveness of several orthoses in the treatment of upper limb involvement of the stroke patient. The gap found in the literature is the ability to join the two treatment modalities - therapy and orthotic management in an effective collaboration. Several articles have appeared in the literature recently describing a newly introduced treatment approach - Constraint-Induced (CI) therapy.^{41, 40, 37, 28, 23} This therapeutic technique has been used on both chronic and sub-acute patients effectively. The therapy involves use of the more affected upper extremity to a target goal of 90% of waking hours. It also involves the practice of reducing the use of the less affected upper extremity. Shaping is the behavioral training technique employed during the therapy time. Its development is

based on the learned nonuse phenomenon first described by Taub⁴¹ In this study, four groups of patients received CI therapy as compared to the control groups. After a period of two weeks there were positive results particularly the improvement in quality of movements of the affected arm. Wolf⁴⁶ and associates used a controlled trial study to test 25 patients and followed them for a period of one year. The result was after undergoing CI therapy techniques, there was an improvement on the speed of task execution. There are studies that do document negative results with the use of CI type therapeutic techniques.⁴³ In these cases where the same technique does not produce favorable results, could the results have been improved with combination use of a therapy technique as well as orthotic intervention? Combined approaches of therapy and orthotic intervention need to be further investigated. Other therapeutic techniques are also reviewed in the literature to have been examined and shown positive results. Functional electrical stimulation (FES) is used in the treatment of hemiplegia for both upper and lower extremity involvement. FES techniques for the lower extremity involve the assistance of gait and limiting synergy patterns by strengthening with FES. With specific application to the upper extremity, FES has been used to stimulate the extensor digitorum communis and the ulnar nerve.¹² The hand can be stimulated to produce hand opening function however no reciprocal motion was facilitated which rendered the motion nearly non functional.¹² FES has also been documented to be effective in preventing shoulder subluxation.⁹ The use of FES in the hemiplegic patient has clearly had some effect on the hemiplegic arm. However, the question then becomes if combined with effective orthotic management, could these physiologic effects made by FES be translated into functional improvements for a patient? Possibilities include the use of the orthokinetic cuff to improve motion and quality of use of a paretic upper extremity.³¹ Treatment for common orthopedic conditions is well documented and well established in the orthopedic literature. Treatment for common orthopedic problems in which the injured arm is hemiplegic is however not as well documented. Carpal tunnel syndrome (CTS) is a common orthopedic affliction. It is treated by splinting to prevent wrist flexion, rest and surgery to alleviate pressure on the median nerve if necessary. The treatment is effective and has become routine for the orthopedic patient. The development and treatment of CTS in the hemiplegic upper extremity is significantly less routine. The association of CTS and hemiplegia was documented by Lo in 1998.²⁵ Treatment described in the case report presented by Lo showed favorable conservative treatment with splinting and resultant decrease of pain. The influence of spasticity, positioning and muscle imbalance must be considered. The decrease of pain that resulted with conservative treatment may influence the functional outcome of rehabilitation. The development of contractures is common in the hemiplegic upper extremity due to the presence of spasticity and abnormal muscle tone that is inherently resistant to passive stretch. Stroke affecting the motor cortex or internal capsule commonly produces hypotonia and absent tendon jerk reflexes followed by several days or weeks of

spastic hypertonia in the antigravity muscles.² The upper extremity in particular develops an adducted position at the shoulder and a flexed position at the elbow, wrist and fingers. Management of upper extremity contracture is an ongoing problem in the orthopedic population. Literature strongly supports static progressive stretching protocols for upper extremity management. Green established static progressive protocols for stretching elbow flexion contractures.¹³ Gelinis in 2000 reported the effectiveness of turnbuckle splinting to treat elbow flexion and extension limitations of range of motion¹⁰. Bonutti³ and O'Driscoll³² also published data to support the effectiveness of static progressive orthotic management to flexion and extension contractures. What has not been effectively documented is the role that spasticity plays on development and treatment of upper extremity contractures. Patients with contractures and spasticity are particularly at risk for skin breakdown and may not tolerate a prolonged amount of time in a static progressive orthosis. The effectiveness of serial casting is well documented by Cruickshank⁷ and Hill¹⁷. A case study was produced recently where patients with mild to moderate spasticity and resultant elbow flexion contractures were treated with two different methods.⁴⁸ One patient was treated with a dynamic based stretching splint, bivalve cast and botulinum toxin (BTX) injection. The other patient served as a control and was treated with serial casting only. Although the results were positive for the patient who received all three interventions, studies with larger subject numbers are necessary to validate this procedure. Air splints are also documented through case studies to produce favorable results in decreasing spasticity.^{33, 44} Literature also supports dynamic splinting protocols³⁶ however dynamic splinting is less commonly used in current clinical practices for contractures of the upper extremity. Dynamic splinting provides a constant load to the affected tissue which becomes altered by the principle of "creep". Creep is defined as the "continual elongation of tissue over time with the application of a constant load"³⁴. Although theoretically this may prove effective to increase range of motion, an inflammatory response is also elicited which can dramatically alter the effects on the joint.³⁰ Although the spastic upper extremity predisposes the hemiplegic arm to contracture development, the area of contracture treatment in the hemiplegic arm is relatively unaddressed in the literature. Although static progressive theory and stretching protocols work well for the non-hemiplegic (non-spasticity involved) arm, a contracture with the complication of the presence of spasticity is less easily resolved. Current techniques of combining the use of botox and dynamic splints were investigated in a case study report with favorable results.⁴⁸ Increased attention and research effort needs to be focused on this problematic area of rehabilitation. Technology provides an approach to updating and improving the existing therapeutic techniques as well as orthotic management. In order to validate new componentry and experimental techniques they need to be subject to research criteria and initiation of control based studies. New technology for stroke rehabilitation of the hemiparetic hand may involve the use of electrical stimulation to increase

hand function as in the use of a hybrid functional electrical stimulation orthosis system as described by Weingarden.⁴⁵ It applies the use of a newly developed FES set up to effect function of a hemiplegic upper extremity affected by spasticity. Ijzerman¹⁹ also described the "Ness Handmaster Orthosis" as a means of restoring hand function in stroke and C5 spinal cord injury patients. Cost analysis of technological aids vs. their functional effectiveness was investigated by Hesse in 1996.¹⁶ Although the amount of functional usage and degree of "gadget tolerance" may vary from patient to patient, the rehabilitation process needs to stay updated to provide patients with as wide a variety as possible. The only means to make this more widely known is through case study reporting as well as publications on experimental and trial systems. Although they may not withstand the scrutiny of controlled trial studies and produce results applicable to the general population of hemiparetic patients, the results of limited use case studies are valuable to the thinking process of creative, active therapists and orthotists. Well documented case studies showing the success of treatment methods or orthotic solutions used in a limited population can later be expanded to more rigorous trials if necessary.

In conclusion, a concerted effort needs to be made to validate some of the innovative techniques recently reported in the literature. The majority of articles are classified as case reports and expert opinions. (Table 1) Very few studies exist that can be classified as grade A recommendations as defined by Shekelle (Table 2). The increased emphasis for evidence based medicine should serve as a catalyst toward achieving this goal. Continued effective communication between therapists, orthotists and other members of the rehabilitation team is necessary for positive outcomes and development of the field of orthotics applied to the upper extremity of the hemiplegic patient.

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LEVEL OF EVIDENCE								
	I	IIA	IIIB	III	IV	V	VI	VII
Bender, L.	•							
Bhatka, B.B.								•
Bonutti, P.M.							•	
Boyd, E.A.								•
Brown, R.A.							•	
Chon, J.-S.							•	
Cruickshank, D.		•						
Dittmer, D.K.								•
Faaghri, P.D.							•	
Gclinas, J.J.							•	
Gracies, J.-M.			•					
Granat, M.H.								•
Greene, D.P.							•	
Hendricks, H.T.							•	
Heonig, H.								•
Hesse, S.						•		
Hill, J.							•	
Hummelsheim, H.								•
Ijzerman, M.J.							•	
Joynt, R.L.								•
Kaplan, M.C.								•
Krebs, H.I.								•
Kunkel, A.							•	
Lee, C.			•					
Lo, J.K.							•	
McGovern, R.	•							
Michaelson, S.M.					•			
Miltner, W.H.R.							•	
Morin, L.					•			
Morrey, B.F.								•
Neeman, R.L.							•	
O'Driscoll, S.W.							•	
Poole, J.L.								•
Richard, R.		•						
Richter, E.F.								•
Shah, M.A.							•	
Sisto, S.A.			•					
Spaulding, S.J.								•
Stefanic, M.								•
Tarkka, I.M.					•			
Taub, E.							•	•
Teasell, E.								•
Van Der Lee, J.H.		•						
Varma, V.							•	
Weingarden, H.P.							•	
Wolf, S.L.							•	
Yan, T.							•	
Yasukawa, A.			•					
Zileli, I.							•	
Zorowitz, R.D.			•					

GRADES OF RECOMMENDATION				
	A	B	C	*
Bender, L.	•			
Bhatka, B.B.				•
Bonutti, P.M.			•	
Boyd, E.A.				•
Brown, R.A.			•	
Chon, J-S.			•	
Cruickshank, D	•			
Dittmer, D.K.				•
Paaghri, PD			•	
Gelinas, JJ			•	
Gracies, J-M.		•		
Granat, M.H.				•
Greene, D.P.			•	
Hendricks, H.T.			•	
Heonig, H.				•
Hesse,S.			•	
Hill, J.			•	
Hummelsheim, H.				•
tjzennan, MJ.			•	
Joynt, R. L.				•
Kaplan, M.C.				•
Krebs, H.I.				•
KunKel, A.			•	
Lee,C.		•		
Lo, J.K			•	
McGovern, R.	•			
Michaelson, .SM				•
Miltaer, W.H.R.			•	
Monin, L.		•		
Neeman, R.L.			•	
O'Driscotl, SW			•	
Morrey, B.F				•
Poole, J.L.				•
Richard, R.	•			
Richter, E.F.				•
Shah, M.A.			•	
Sisto, S.A.		•		
Spaulding, SJ.				•
Stefanic, M.				•
Tarkka, I.M.		•		
Taub, E.				•
Teasell, E.				•
Van Der Lee. J.H.	•			
Varma, V.			•	
Weingarden, H.P.			•	
Wolf, S.L.			•	
Yan,T.			•	
Yasukawa, A.		•		
Zileli. I.			•	
Zorowitz, R.D		•		

* Good practice point recommended best practice based upon clinical experience of the guideline development group

SERVICE ISSUES - WHO PRESCRIBES AND WHO PROVIDES? (R15)

David N. Condie BSc., C. Eng. Consultant Clinical Engineer

INTRODUCTION

The reviewer was asked to consider the subject area "Service Issues" and in particular to provide recommendations regarding the two specific questions "who prescribes and who provides (orthoses)".

The literature survey conducted by the organisers identified sixty three (63) journal articles considered to be relevant to this topic however initial inspection revealed that eight only contained specific reference to the questions posed. Of these eight publications two (5,6) are RCTs (study type II), one (3) is a cohort study (study type III), one (8) is a survey (study type V), one (1) is based on expert opinion (study type VII) and three (2,4,7) are literature reviews which cannot be classified. Consequently as indicated in Table 1 the findings may in only two instances be graded A, in one instance be graded B and in one instance be graded C.

Unfortunately none of the scientifically supported findings in any of these papers relate directly to the two questions being considered by the reviewer.

In view of this situation the reviewer has considered it appropriate and necessary to augment the available published evidence with his personal opinion based on 30 years experience as the founder and manager of a general orthotic service including more than 10 years as a member of an orthotic clinic team providing a service to both a medical unit treating acute stroke patients and a geriatric unit where many of the patients were post acute and chronic stroke patients.

For reasons which will become apparent, it is the reviewer's opinion that it is appropriate to address initially the question of who provides an orthosis to a stroke patient before moving on to consider the issue of who should prescribe the orthosis.

Grade of Recommendation Reference

A	(5)	Ozdemir et al
	(6)	Slade et al
B	(3)	Sullivan et al
C	(8)	McMillan et al

Table 1.

Who provides the orthosis?

By common assent the lower limb orthosis most commonly provided to stroke patients is an ankle-foot orthosis (AFO). The indications for such a prescription are variously described as "to prevent spasticity or contractures"(1), "for ankle or knee stabilization"(1) and "to help initiate ambulation"(2). In the reviewer's experience and opinion an AFO is most commonly supplied to stroke patients to achieve all three of these objectives. Firstly it is supplied to resist the abnormal muscle activity which would otherwise result in an abnormal ankle-foot alignment. As a consequence of this action the stability of the ankle (and perhaps the knee) is enhanced and ambulation made safer and easier. Sulli-

van et al (3) report a high utilization of AFOs supplied to stroke patients both in an institutional setting and through an outreach programme.

The design and fit of an orthosis intended to achieve these objectives is crucial. Two categories of orthosis are widely available: pre-fabricated (or stock) orthoses and individually fabricated (or custom-made) orthoses.

Several published studies have demonstrated the relationship between the mechanical characteristics of the AFO provided and the quality of the gait pattern attained by the user. No evidence however has been published comparing the effectiveness of pre-fabricated and individually fabricated orthoses.

It is the reviewer's experience and opinion that in the vast majority of instances when supplying an ankle-foot orthosis to a stroke patient that it is necessary to employ an individually fabricated orthosis in order to achieve the optimum outcome for the user.

Pre-fabricated orthoses, which in many instances are supplied by therapists are seldom capable of providing the type and degree of control necessary to achieve the same benefits.

The consequence of this opinion is that it is necessary to utilise the services of an appropriately trained professional i.e. an orthotist to provide an optimally fabricated, fitted and functioning orthosis for this group of users.

Who prescribes the orthosis?

Now that an opinion has been proposed as to who should most appropriately provide an orthosis to a stroke patient it is possible to move on to the question of who should be responsible for its prescription.

The provision of an orthosis to a stroke patient is considered by some to be a discrete intervention or "component of care"(4) and by others to be supplementary to other forms of training or therapy (1). Where the latter view is held the decision to provide an orthosis and as a consequence the decision regarding the prescription is most likely to be taken by a physician or therapist who is unlikely to have any formal training in orthotics (5,6).

Fortunately modern rehabilitation practise for stroke patients increasingly involves an interdisciplinary team whose common aims are to identify the deficits caused by the stroke and to base the rehabilitation process on this knowledge (7). Clearly this should include any decisions regarding the use of orthoses.

From this conclusion to the proposal that the orthotist (who after all is going to be asked to provide the orthosis) should be a member of this interdisciplinary team seems a logical step and indeed is supported by more than one author (7,8).

No evidence has been published comparing the outcome of the two different models for the prescription of orthoses described above. It is however the reviewer's firm view that

the decision to employ an orthosis to achieve a particular goal(s) should be a team decision. Inevitably the orthotist (who should be an expert in this field) with his or her special knowledge of the capabilities and limitations of currently available designs will play an influential role when making this decision. Thereafter it is clearly the specific responsibility of the orthotist to design and (as has previously been proposed) provide an orthosis which will most effectively achieve these goals.

Other Service Issues

There are a few other service issues which are not specifically addressed by other reviewers and which are directly related to the principal issues discussed in this review.

Once an orthosis has been supplied, hopefully following the practices described above, the orthotic supply process is not finished. All orthotic fittings require to be reviewed and this is particularly important with users who have a neurological lesion who may have a sensory deficit and whose status is likely to change with time. A review schedule must be established on an individual basis for each user which will satisfy two objectives. Firstly to ensure the fit, function and mechanical integrity of the device (sometimes referred to as a "technical" review) and secondly to assess the continuing appropriateness of the prescription

(a "clinical" review. The first of the objectives may be fulfilled by the orthotist alone however a clinical review properly requires the presence of the team..

Records of orthotic treatment are notoriously vague and incomplete. In the past this has been partially attributable to the absence of generally accepted terminology to adequately describe the treatment. The International Standards Organisation (ISO) has since 1989 published (and continues to develop) a number of standards (9,10,11,12) designed to permit the clinical objectives, the functional characteristics and the specific components of orthoses to be accurately described. There is therefore no longer any excuse for not maintaining detailed records of orthotic prescriptions. It is now also generally accepted that the maintenance of complete records of any treatment provided is an integral part of the clinical duties of the orthotist like any other healthcare professional.

A final word must be reserved to stress the importance of the "team" in the orthotic treatment of stroke Although this author has strongly advocated the role of the orthotist in formulating the detailed prescription and as the provider of the device he is equally adamant in declaring the primacy of the team in identifying the appropriate timing of orthotic treatment, defining the objectives of treatment and as previously stated for the continuous assessment of the effectiveness and appropriateness of the treatment .

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OUTCOME MEASURES FOR ORTHOTIC INTERVENTION IN STROKE REHABILITATION (R17)

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Valerie M Pomeroy PhD, BA, FCSP, GradDipPhys

INTRODUCTION

Outcome measures need to evaluate the specific objectives and actions of the intervention provided¹ as well as other aspects of impairment, functional activity and/or participation². For patients improvement is best recognised in terms of their ability to perform activities in everyday life or participate in some desired role³.

Orthotic devices have essentially three aims of correction, protection or restoration (assistance and/or substitution)⁴. Within this categorization the specific aims of the prescription of orthotic devices are reported to be⁵⁻¹³:

1. To relieve pain;
2. To immobilise musculoskeletal segments by limiting/directing joint motion;
3. To reduce axial load/protect joints;
4. To enhance stability of joints;
5. To increase awareness;
6. To decrease energy expenditure;
7. To prevent or correct deformity/improve structural alignment;
8. To influence alignment of other joints during functional activity;
9. To improve function e.g. static and dynamic balance, toe clearance during the swing phase of gait, heel strike.

This list of aims combined with the requirement to measure indirect aims and aspects of function/participation important to patients highlights the need for a variety of outcome measures to evaluate orthotic devices in people following stroke.

Clearly there is much that can be measured to evaluate the effects of orthotic devices but it is neither feasible nor desirable to measure everything. The first step is therefore to select outcome tools that firstly match the aims of the intervention, and secondly which demonstrate acceptable measurement properties. Wade (pp35-43)¹⁴ suggests that outcome measures need to possess the key attributes of validity, reliability, and sensitivity. A measure is valid when it assesses what it is intended to measure. Reliability refers to the ability to reproduce the results of the measure, and sensitivity relates to its' ability to detect anticipated changes. In addition, outcome measures need to demonstrate feasibility i.e. simple to use, resource friendly, providing data with ecological validity defined as "the suitability of the measure in the environment it is to be used in"¹⁴.

AIMS

The aims of this review are:

1. To determine whether published studies of orthotic intervention for adults after stroke have used outcome measures that were appropriate in terms of the aim of intervention, reliability, validity, sensitivity and feasibility.
2. To identify some additional appropriate outcome measures
3. To compile a suggested core battery of outcome measures which should be considered for use in evaluative studies of orthotic intervention for adults after stroke

METHODS

Potentially relevant studies, including all designs, were identified by searching the following databases and searching our own private collections of published papers (aim 1):

- RECAL Bibliographic Database using the terms: stroke, cerebral vascular accident, hemiplegia, spasticity, disability outcome, measure, assess, evaluate, instrument, estimate, therapy and rehab;
- MEDLINE 1966 to June 2003 using the terms orthotic devices and cerebrovascular accident;
- EMBASE 1980 to June 2003 using the terms orthotics (exp) and cerebrovascular disease/rehabilitation (exp);
- CINAHL 1982 to June 2003 using the terms orthoses (exp) and cerebral vascular accident/rehabilitation (exp);
- AMED 1985 to June 2003 using the terms orthotic devices (exp) and cerebrovascular disorders (exp).

This part of the review targeted studies, which aimed to evaluate the effects of orthotic intervention in adults following stroke. Orthotic devices are defined in this paper as: "devices that are applied to the external surface of a body part"⁸. Each author independently identified papers that reported a study evaluating the use of orthotics with stroke patients on the basis of reading the titles and abstracts. Studies evaluating FES were excluded. One author (VP) focused on outcome measures of impairment (subdivided into impairment and movement performance), whilst the other (SL) concentrated on measures of functional ability/participation.

As a large number of different measures were identified it was not possible to assess all of them with systematic reference to the research literature for their measurement properties. The number of outcome measures for assessment was reduced by excluding outcome measures which:

- used objective instrumentation and had face validity, in the judgment of the authors;
- were based on clinical report or visual inspection.

All remaining outcome measures were then assessed with reference to the list of therapeutic aims and the key attributes of validity, reliability, sensitivity and feasibility¹⁴. This assessment was informed by undertaking a second electronic search of Medline and CINAHL to identify studies investigating the measurement attributes of the identified measures. This search was supplemented through reference to our own databases of papers relating to outcome measurement. For this review, assessment of reliability and concurrent validity was made with reference to the recommended form of analysis which is to calculate either intra-class correlation coefficients (ICC) from an analysis of variance model (ANOVA)¹⁵ together with the limits of agreement to indicate the region within

which 95% of differences can be expected to fall¹⁶ or to calculate percentage agreement together with the Kappa Coefficient¹⁷. An acceptable ICC/Kappa value was held to be 0.75 or above¹⁸. Any disagreements were resolved through referral to full papers and discussion between the authors.

RESULTS – IDENTIFICATION OF INCLUDED STUDIES OF ORTHOTIC DEVICES

The RECAL search identified 253 publications (including 100 published abstracts) of which 11 were considered to meet the criteria for this review. The other searches identified a further 15 relevant papers. The twenty-six studies selected are summarised according to study design, aim, type of orthotic device, and chosen outcome tools in Table 1.

Study ID	Source	Aim of intervention	Type of Orthotic	Outcome measures used
Aruin 2000 ¹⁹	RECAL; CINAHL	Adding a shoe lift to the (UA) leg to improve symmetrical weight-bearing by forcing weight over to the (A) leg.	Shoe lifts	<ul style="list-style-type: none"> • Symmetry of weight bearing (vertical force) through lower limbs in standing using Balance Master; • Gait velocity; • Step length;
Beckerman 1996a ²⁰	RECAL; AMED	Investigate the effects of tibial nerve coagulation and an ankle AFO on spastic equinus or equinovarus feet over a 15 wk period	AFO	<ul style="list-style-type: none"> • Spasticity differentiated by slow or quick passive movements of the foot; • Muscle tone - Ashworth Scale; • Reflex activity - Achilles; ankle clonus; • Range of motion - plastic goniometer; • Fugl-Meyer Assessment Scale for lower limb motor function, sitting and standing balance;
Beckerman 1996b ²¹ (Same data as above?)	AMED; CINAHL	Investigate the effects of tibial nerve coagulation and an ankle AFO on walking ability over a 15 wk period	AFO	<ul style="list-style-type: none"> • Walking ability - Sickness Impact Profile Category; • Gait velocity; • Patient satisfaction and compliance
Burdett 1988 ²²	MEDLINE	To determine the effects of the AS brace vs an AFO on walking ability	Air-Stirrup Brace (AS)	<ul style="list-style-type: none"> • Temporal-spatial gait parameters using an inked walkway and a digital stopwatch in video camera; • Lower limb joint angles using videotape of walking and a goniometer on the video monitor screen
Chang & Su 2000 ²³	MEDLINE	To describe a new design allowing barefoot walking	Anterior encased AFO to allow barefoot gait	<ul style="list-style-type: none"> • Clinical visual standing posture and gait analysis; • Patient report of security and satisfaction; • Clinical report of mobility and self-care;
Chaudhuri & Aruin 2000 ²⁴	RECAL	To determine the effects of shoe lifts to the (UA) leg on weight-bearing symmetry & response latency/strength to unexpected translations	shoe lifts	<ul style="list-style-type: none"> • EquiTest movable force platform for: • Weight symmetry scores in quiet standing; • Response latency in perturbed standing; • Response strength in perturbed standing
Chen 1999 ²⁵	RECAL	The effects of AFOs' on static & dynamic postural stability	Anterior AFO	<p>Computer Dyno Graphy System using two "shoes" each with 8 load sensors:</p> <ul style="list-style-type: none"> • Standing stability; • Dynamic - max limit of COP (X-Y co-ordinate) of movement A/P, M/L; • Vertical force under each foot;

De Vries 1991 ²⁶	AMED	To evaluate the risk of falls when using AFOs' and walking aids	Lower leg orthosis	<ul style="list-style-type: none"> MRC muscle strength score as a basis for clinical levels of leg motricity;
Dieli 1997 ²⁷	AMED	The effect of a DAFO on gait	dynamic AFO (DAFO) Plantarflexion stop	<ul style="list-style-type: none"> VA-Rancho Stride Analyzer (uses footswitches worn as soles) for: Gait velocity; Temporal distance parameters
Fujimoto 1999 ²⁸	RECAL	The use of KAFOs' as training orthoses for severely flaccid stroke patients to promote standing & walking	Knee AFOs	<ul style="list-style-type: none"> FIM
Gok 2003 ²⁹	OWN	The effects of two types of AFO on gait	Metalic and plastic AFOs	<p>Vicon 370:</p> <ul style="list-style-type: none"> Gait velocity; Temporal distance parameters Knee flexion moment Ankle angle at HS and mid-swing
Grissom & Blanton 2001 ³⁰	MEDLINE	The effect of an AFO on reducing plantarflexion contracture for 14 days	Adjustable AFO	<ul style="list-style-type: none"> Passive range of movement into dorsiflexion with plastic goniometer
Isakov 1992 ³¹	AMED	The effect of an KAFO vs an AFO on gait	Swedish knee cage and AFO	<ul style="list-style-type: none"> 10m walkway fitted with electrical contact system: Stance time; Stride length; Gait velocity;
Iwata 2003 ³²	OWN	To test whether an inhibitor bar to reduce tone on an AFO improves walking ability	AFO with inhibitor bar over a 2 week period	<ul style="list-style-type: none"> Spasticity plantarflexors - Modified Ashworth Scale; 10m walk timed with stopwatch; Cadence using a counter; Stride length estimated from velocity and cadence;
Kakurai & Akai 1996 ³³	AMED	The effect of KAFO on walking ability	KAFO and AFO	<ul style="list-style-type: none"> Ambulation category; Modified Barthel Index;
Kosak & Reding 2000 ³⁴	CINAHL	To compare treadmill training with PBWS to brace assisted walking over 12 sessions	Bracing lower limbs	<ul style="list-style-type: none"> Walking endurance = distance until patient fatigued; Gait velocity = mean speed over 2 minutes
Moon 2002 ³⁵	RECAL	The effect of shoe lift on the (UA) side on plantar pressure & WB symmetry	Shoe lifts	<ul style="list-style-type: none"> Insole pressure measurement of plantar pressure;
Mueller 1992 ³⁶	RECAL	The effect of a DAFO on foot loading patterns for a 14 week period	Dynamic AFO	<ul style="list-style-type: none"> EMED-SF to measure plantar pressure of hindfoot, midfoot and forefoot for: Total foot force; Total foot area; Total foot contact time
Rodriguez & Aruin 2002 ³⁷	CINAHL	The effects of a shoe wedge vs shoe lift in promoting stance symmetry	Shoe wedges and lifts	<ul style="list-style-type: none"> Balance Master for symmetry of weight bearing (WB) through lower limbs in standing
Rodriguez & Aruin 2000 ³⁸ (same data as above?)	RECAL	The effect of 3 different wedges on the (UA) leg on weight-bearing over the (A) leg	Angled shoe wedge	<ul style="list-style-type: none"> Balance Master for symmetry of weight bearing through lower limbs in standing

Scherling & Johnson 1989 ³⁹	AMED	To reduce tone	Dynamic dorsal wrist-hand orthosis worn for a minimum 4 hr period daily	<ul style="list-style-type: none"> • Passive range of movement in shoulder; • Muscle tone in hand; • Pain in upper limb; • ADL; • position of thumb; • posture of radial grasp; • ability to bear weight through heel of hand with elbow extended;
Sullivan 1990 ⁴⁰	AMED; CINAHL	To what extent do stroke patients use their AFO?	AFO	<ul style="list-style-type: none"> • questions on mobility; • Patients' use of AFOs; • Perceived comfort; • Perceived usefulness;
Teasell 2001 ⁴¹	RECAL; AMED; CINAHL	To examine factors associated with the use of AFOs'	AFOs	<ul style="list-style-type: none"> • Chedoke-McMaster Stroke Impairment Inventory (CM); • Berg Balance Score (BB); • FIM;
Tyson & Thornton 2001 ⁴²	AMED; CINAHL; MEDLINE	The effect of a hinged AFO worn for one month on gait	Hinged AFO	<ul style="list-style-type: none"> • Functional Ambulation Categories; • Patients' opinions • Inked paper walkway for: Temporal distance parameters
Woodson 1987 ⁴³	CINAHL	To describe the clinical use of a splint for the hemiplegic hand	Hand splints with finger separators to reduce tone	<ul style="list-style-type: none"> • Voluntary range movement in joints/segments; • Hand grasping function; • Muscle tone; • Fractionated movement; • Functional activity;
Woolley 1996 ⁴⁴	RECAL	To compare the balance & walking ability of patients wearing both an AFO & A DAFO	AFO vs DAFO Worn for a 4 month period	<ul style="list-style-type: none"> • Static balance on force platform; • Temporal-spatial gait parameters; • Ground reaction forces during walking;

Table 1. Summary of included papers: identification source, orthotic evaluated and outcome measures used

Table 1 confirms that the research literature is both sparse and of variable quality in relation to orthotic intervention following stroke. There were only two randomized controlled trials (RCT) with a combined sample of 116 subjects^{20,34}; the majority of trials were pre-post test designs with less than 10 subjects in five of these trials. Only 2 studies were specific to the use of orthotics for the upper limb^{39,43}; both are case reports. The studies specific to the lower limb support the recommendation of the UK National Clinical Guidelines for Stroke⁴⁵ that the evidence for AFOs' is inconsistent, although AFOs' may be of benefit to some patients (level IIa, grade B).

RESULTS – APPROPRIATENESS OF THE OUTCOME MEASURES USED IN PUBLISHED STUDIES TO THE AIMS OF THE ORTHOTIC INTERVENTION

The studies identified had five main aims: to reduce tone, to improve weight-bearing on the paretic lower limb, to improve postural control, to reduce contracture, and to improve function. There were seven studies related to the reduction of tone; five involved the lower limb and two the hand. Surprisingly only four studies actually measured tone (Table 1)^{19,32,39,43}. Six studies aimed to improve weight-bearing on the paretic lower limb (Table 1)^{22,24,25,35,37,38}. None of these studies examined the impact of this treatment strategy on walking ability. Two studies

investigated postural control (Table 1)^{24,25}. Chaudhuri and Aruin²⁴ used a movable force platform and Chen and colleagues²⁵ used a system with two “shoes” each with eight load sensors. Only one study examined the effect of orthotic devices on the reduction of contracture (Table 1)³⁰. Degree of contracture was assessed by measuring passive range of motion into dorsiflexion using a plastic goniometer. Nine studies have investigated the effect of AFOs' on walking ability using a range of outcome tools such as movement patterns, velocity and clinical scales (Table 1)^{21-23,28,29,31,33,34,42}. Only two studies have measured foot drop during gait^{22,29}. In summary, the majority of studies have chosen appropriate measures of impairment matched to the aims of orthotic intervention tested, except in the case of studies aiming to reduce tone; however many studies have not monitored these effects at the level of walking function.

RESULTS – MEASUREMENT PROPERTIES OF OUTCOME MEASURES USED IN PUBLISHED STUDIES

Measures of impairment

The majority of outcome measures were excluded from systematic assessment on the basis of the exclusion criteria listed in the Methods section above. The three remaining measures were muscle strength as measured by the MRC score, abnormalities of muscle tone as measured by the

Ashworth Scale and composite impairment as measured by the Chedoke McMaster Stroke Impairment Inventory. The results of the analysis are provided in Table 2 and details are given below.

	Validity	Ecological	Reliability		Sensitivity
	Face/ Concurrent		Clinical/ research	Inter-rater	
Muscle strength MRC Scale	√/?	√/?	?	?	No info found
Muscle tone Ashworth Scale	?/No info found	√/?	?	?	No info found
Impairment Chedoke McMaster	?/?	√/√	?	?	No info found
Movement Inked walkway	?/No info found	?/?	No info found	No info found	No info found

Table 2: Summary of measurement properties for outcome measures of impairment

a. MRC Score to measure muscle strength²⁶

To identify studies of measurement of muscle strength using the MRC Score the MEDLINE and CINAHL electronic search used the key words: muscle, measurement, and, MRC. Only one study was identified. Face validity seems reasonable and the MRC score is relevant to therapeutic aims of using orthotic devices. Ecological validity also appears reasonable in the clinical setting although more precise measurement may be required for research activity. No research information was found on sensitivity or concurrent validity. In terms of reliability Gregson and colleagues⁴⁶ found that between different joints;

- intra-rater percentage agreement ranged from 37% to 61% and quadratic weighted Kappa ranged from 0.70 to 0.96
- Inter-rater percentage agreement ranged from 26% to 61% and quadratic weighted Kappa ranged from 0.84 to 0.96.

Although these Kappa values appear reasonable, mostly being 0.75 and above, it should be appreciated that quadratic weighted Kappa, despite statistical validity, may give an inflated impression of the real clinical agreement⁴⁷. A suggestion supported by percentage agreement values as low as 26%⁴⁶. The MRC Score may or may not have acceptable reliability for measuring muscle strength around some joints.

b. Ashworth Scale to measure abnormalities of muscle tone³²

To identify studies of measurement of muscle tone using the Ashworth Scale the MEDLINE and CINAHL electronic search used the key words: muscle, measurement, and, Ashworth. One experimental study was identified. Face validity seems reasonable for normal or high tone although low tone cannot be measured with the Ashworth Scale,

which is a disadvantage after stroke. Measurement of abnormal tone is relevant to therapeutic aims of using orthotic devices. Ecological validity also appears reasonable in the clinical setting although more precise measurement may be required for research activity. No research information was found on sensitivity or concurrent validity. Reliability data relating to several joints is extracted from the study reported by Gregson and colleagues⁴⁶:

- intra-rater percentage agreement ranged from 50% to 79% and quadratic weighted Kappa ranged from 0.59 to 0.94
- Inter-rater percentage agreement ranged from 38% to 78% and quadratic weighted Kappa ranged from 0.45 to 0.96.

As for the MRC Score for muscle strength it needs to be appreciated that the statistical analysis used might give an inflated impression of real clinical agreement⁴⁷; therefore the Ashworth Scale may or may not have acceptable reliability for measuring muscle tone.

c. Chedoke McMaster Stroke Impairment Inventory to measure composite impairment⁴¹

To identify studies of measurement of composite impairment the Chedoke McMaster Stroke Impairment Inventory the MEDLINE and CINAHL electronic search used the key words: muscle, measurement, and Chedoke McMaster. This search identified one study. Face validity is apparent from the content of the Chedoke McMaster Stroke Impairment Inventory which includes pain, range of joint movement and muscle strength⁴⁸ and all areas appear relevant to the therapeutic aims of using orthotic devices. Ecological validity also appears reasonable in the clinical and research setting (depending on the aim of individual studies). No research information was found on sensitivity or concurrent validity. Reliability data is presented by Gowland and colleagues⁴⁸ as:

- Intra-rater reliability ICC of 0.98 (0.95 lower confidence interval);
- Inter-rater reliability ICC of 0.97 (0.94).

However, Chedoke McMaster Stroke Impairment Inventory data are ordinal rather than nominal or ratio and therefore a more appropriate statistical test would probably be the Kappa coefficient. Gowland and colleagues⁴⁸ also investigated concurrent validity but insufficient data was provided about the correlation coefficients used for analysis. No research information was found relating to sensitivity to change.

2. Measures of movement performance

Table 3 identifies the outcome measures of movement performance (impairment) across studies, usually involving motion analysis data such as symmetry; ground reaction force during walking; plantar pressure; joint moments and angles during walking; and temporal spatial gait parameters.

The only outcome measure remaining after the exclusion of motion analysis data, which use objective instrumentation and have obvious face validity criteria, was the inked

walkway However it is important to note that instrumented, often lab-based methods of measuring performance of movement may be unavailable in the clinical setting.

a. Inked walkway

To identify studies of measurement of temporal-spatial gait parameters using an inked walkway the MEDLINE and CINHALL electronic search used the key words: ink and walk. This search failed to identify any studies. Face validity seems evident as the ink prints left on the paper relate exactly to a patient's footprints. However, it seems reasonable to propose that if foot dragging is part of a walking pattern that the paper might distort or tear and thus

affect the measurements made from the ink record. There could be some walking patterns therefore that cannot be measured with the ink walkway method. Nevertheless, when walking patterns are suitable to be measured with this method, both clinical and research ecological validity appears reasonable although the processing of data can be time consuming. It seems self evident that the measurement of temporal spatial gait parameters is relevant to the therapeutic aims of providing orthotic devices. In terms of reliability, concurrent validity and sensitivity we did not find any research data to inform a decision about the appropriateness of using an inked walkway to evaluate orthotic devices.

	Standing posture & stability	Ground reaction force & Plantar pressure & Joint moments	Joint angles & voluntary ROM	Temporal spatial gait parameters including gait velocity & endurance	Quality & Symmetry walk
Aruin 2000 ¹⁹	Balance Master			Yes	
Beckerman 1996b ²¹				Infra-red beams	
Burdett 1988 ²²			Video + goniometer	Stopwatch Ink walkway	
Chang 2000 ²³	Visual inspect				
Chaudhuri 2000 ²⁴	EquiTest				
Chen 1999 ²⁵	Forceplate				
Dieli 1997 ²⁷				VA-Rancho	
Gok 2003 ²⁹		Forceplate	3D system	3D system	
Isakov 1992 ³¹				Instrumented walkway	
Iwata 2003 ³²				Stopwatch + count	
Kosak 2000 ³⁴				Fatigue distance	
Moon 2002 ³⁵		Insoles			
Mueller 1992 ³⁶		EMED-SF		EMED-SF	
Rodriguez 2002 ³⁷	Balance Master				
Rodriquez 2000 ³⁸	Balance Master				
Scherling 1989 ³⁹					Clinical report
Tyson 2001 ⁴²				Inked walk	Inked walk
Woodson 1987 ⁴³			Clinical report		Clinical report

Table 3: Summary of movement performance measures used across studies

3. Outcome measures of functional ability

Six clinical scales of function were employed in five out of twenty-six studies: the Barthel Index³³; the Berg Balance Score⁴¹; the Fugl-Meyer Assessment²⁰; the Functional Ambulation Category (FAC)^{33,42}; the Functional Independence Measure (FIM)^{28,41}; and the Sickness Impact Profile (SIP)²⁰. A further search of AMED, CINAHL and MEDLINE databases from 1995 to June 2003 using the name of each of these scales combined with reliability, validity and stroke identified the following number of hits:

- Barthel Index (2 out of 51 hits)
- Berg Balance Score (7 out 14 hits)
- Fugl-Meyer Assessment (2 out of 22 hits)
- Functional Ambulation Category (0 hits)
- Functional Independence Measure (8 out of 26 hits)
- Sickness Impact Profile (2 out of 43 hits)

The measurement attributes of these scales are presented in Table 4.

Measure	Validity	Intra-rater Reliability	Inter-rater Reliability	Sensitivity	Feasibility
Barthel Index (BI)	√ / gold standard	0.70-0.88 (Kappa)	0.98 (Kappa)	?	*No equipment *5-15 minutes *minimal training
Berg Balance Score (BBS)	√ / √	0.98 (Kappa)	0.99 (Kappa)	+/- 6 points	*some equipment *10-20 minutes *some training
Fugl-Meyer Assessment (FMA)	√ / weak for UL strong for lower limb	0.86 for LL (ICC)	0.92 for LL (ICC)	+/- 9.4 pts (total) +/-3.6 pts (lower limb)	*some equipment *30-40minutes *therapist-oriented
Functional Independence Measure (FIM)	√ / √	0.96 (Pearson)	0.96 (Kappa)	?	*some equipment *45 minutes *team training required *cost for purchase & use
Sickness Impact Profile (SIP)	√ / √	0.75-0.97 (Kappa)	?	?	*no equipment * 20-30 minutes * training is required *cost for use

Table 4: Measurement attributes of clinical scales aimed at function

Berg Balance Score (BBS; Finch and colleagues, p. 93)³

The BBS contains 14 items related to balance with each item scored from 0 to 4 for a maximum score of 56. It measures both the ability of patients to remain upright and to adjust to displacement. It is a timed test. Subjects with a score of 36 and below are at risk of falling. Further information can be obtained at: www.chcr.brown.edu/BALANCE.HTM. It combines both impairment and functional items of balance and therefore could be useful for studies of orthotic intervention.

Barthel Index (BI; Finch and colleagues, p87)³

This index is a measure of personal care. The original index consists of 10 items of self care scored between 0-100 with a higher score representing a higher level of independence. Each item is assigned a score of 0, 5, 10 or 15 with each item weighted differently. Wade¹⁴ recommends using a modified version which contains the same 10 items with a simplified scoring system ranging from 0 to 3 for a total score of 20. It can be administered in 10 to 20 minutes by any health care professional. The BI has been used as a gold standard for validation of other scales many times. Only the walking, stairs and transfer items would be relevant to orthotic intervention. There are better outcome measures of functional ability for studies of orthotic intervention.

Fugl-Meyer Assessment (Finch and colleagues, pp.136)³

This measure has three independent sections, which are impairment of the upper & lower limb, balance and sensation. Each item is scored from 0-2; the upper limb subscore is 34; the lower limb sub-score is 34 for a total motor score of 100. The balance section contains 7 items of which 4 take place in standing for a score of 14. The total score for all sections is 226. The FM is based on Brunnstrom's stages of recovery suggesting that recovery occurs in a predictable sequence with the return of reflex mass patterns preceding voluntary activity. These ideas are no longer well supported by current theories of motor control or studies of recovery. Therapy

in Europe is not based on the Brunnstrom approach; this scale would not be preferred for use in European Studies. Collen⁴⁹ in a review of measurement of standing balance, identified two problems with the FM (balance) section, it does not discriminate between performance in sitting and standing, and its' inter-rater reliability is low. It is not one of the better outcome measures for use following orthotic intervention.

Functional Ambulation category⁵⁰

This is a simple classification based on the level of assistance required by an individual to walk ranging from 0 meaning that the patient either cannot walk or requires the assistance of 2 people to 5 where the patient can walk independently anywhere. It does not take into account walking aids. It is a useful, simple measure of the amount of physical support needed to walk and could be useful in orthotic intervention studies. Collen and colleagues⁵⁰ confirmed that its' inter-rater reliability was low (0.36-Kappa), and it was insensitive to change. There are better outcome measures of walking ability for studies of orthotic intervention.

Functional Independence Measure (FIM; Finch and colleagues, p.144)³

The FIM was developed by a National Task Force in America in 1984 to provide an estimate of the burden of care. It is a proprietary measure for which information can be obtained at: www.udsmr.org. There are 13 motor items and 5 cognition items; each rated on a seven level scale. The total score ranges from 18 (lowest) to 126 (highest). An average improvement between admission and discharge for people after stroke rehabilitation is 25 points. Its' selling point is that it is widely used and therefore allows comparison across research studies. There are other outcome measures of walking ability, which would yield more detailed information for studies of orthotic intervention

Sickness Impact Profile (SIP; Finch and colleagues, p.220)³

The SIP, also known as the Functional Limitations Profile, is a generic questionnaire containing 136 statements grouped and scored into 12 categories. Three of these categories (ambulation; body care and movement, and mobility) can be combined into a physical dimension; all of these would be relevant to orthotic intervention. Scores for each category range between 0 to 100; a higher score indicates a greater level of dysfunction. It can also be self-administered. It is published in Wade¹⁴, but should be obtained from the developers. The SIP is similar to the FIM, it is probably preferable to use the FIM, which is more widely used and therefore allows comparison across research studies.

DISCUSSION

This review has highlighted that many different outcome measures have been used across studies of orthotic intervention after stroke; it is reassuring to note that most studies have used outcome measures that meet the key attributes of validity, reliability and sensitivity. However

it is striking that only a few studies have complemented outcome measures focused on impairment with outcome measures aimed at the level of disability. The majority of studies focused on impairment have used lab-based measures, which cannot be feasibly transferred to the clinical setting (see Table 3). Although many measures that are currently lab-based might not have ecological validity for clinicians there are objective, instrumented measures that could be used outside the gait laboratory i.e. instrumented walkways to measure temporal-spatial parameters of gait. Inter-rater reliability is acceptable however, it is possible that this might be reduced when stroke patients exhibit more abnormal gait patterns e.g. GaitMat II⁵¹.

Measuring impairment

This review found that relatively few neurophysiological measures were used in the included studies. This is surprising in the light of evidence that specific interventions may induce brain plasticity after stroke in patients, not only in the sub-acute phase but also in the chronic phase of recovery (reviewed by Calautti and Baron⁵²). It is possible that neurophysiological measures are not numerous because many rehabilitationists tend to favour movement and functional outcome measures in view of their commitment to giving priority to what matters to patients and to a holistic approach. In the case of the use of orthotic devices after stroke an holistic approach requires consideration of the use of measures of neurophysiological impairment⁵³. Information about the mechanisms underlying clinical change is important for evaluating attempts to improve outcome, as it gives insight into what, if anything has actually happened to the patient's nervous system. Understanding the effects of physical therapies on the nervous system requires utilization of neurophysiological tests⁵³. Is it sufficient to know that function has changed or would it be better to know what the underlying mechanisms of that change are so that further efforts could be made to produce more change with the aim of even better function?

Measuring outcome of function

This review identified six functional outcome measures in use across studies; however when matching the outcome measure chosen to the aim of orthotic intervention only the BBS would seem appropriate in terms of measuring stability in standing. The other measures reported are global measures of disability with only a small number of items specifically related to orthotic intervention; amongst these, the FIM would appear to be the better choice of outcome tool used however there are many other clinical tools of balance and mobility which offer a better choice for outcome measurement following orthotic intervention. Only one of these 6 measures would be able to demonstrate change in relation to the upper limb (FMA). It is beyond the scope of this review to identify all appropriate outcome measures for orthotic intervention. Two excellent reviews provide a starting point for selecting appropriate outcome measures for orthotic intervention^{3,14}. A few other measures are worthy of mention in relation to stroke rehabilitation. In a review of measures of standing balance after stroke,

defined as the ability to stand and move in an upright position, Collen and colleagues⁴⁹ recommended the timed get up and go (TUG) or 10 metre timed walk. The TUG times an individual's ability to stand up, walk for 3 metres, to turn, walk back and sit down; it is scored on a scale of 1 (normal) to 5 (abnormal). The range of times reported for healthy, older people is 7 to 10 seconds⁵⁴. In a further review, Bernhardt and colleagues⁵⁵ following the implementation of a range of outcome measures of balance and gait in a sample of 29 patients undergoing inpatient rehabilitation after stroke, suggest using one component of the Clinical Test of Sensory Interaction of Balance (CTSIB), the Repetitive Reach Step Stance Test, the Step test (ST) and gait velocity. Of these measures, the ST⁵⁶ and gait velocity⁵⁴ would appear most suited to orthotic intervention studies. The ST evaluates dynamic single limb stance. The ST would be useful in orthotic intervention; it involves stepping on and off a 7.5 cm block within a 15 second period, and healthy older people can complete a mean 17 to 18 steps in 15 seconds. It provides a simple clinical test of both stance and swing phase ability, especially useful when assessing the effect of an AFO for foot drop.

A recent study by Salbach and colleagues⁵⁴ reviewed the responsiveness of gait speed and other disability measures in acute stroke [TUG, BBS and the Stroke Rehabilitation Assessment of Movement (STREAM)]. They recommended the 5 m walk test as the measure of choice to detect longitudinal change in walking ability in the first 5 weeks after stroke. It is important to note that the best choice of test depended on the level of recovery, the three most responsive measures for the fast group (0.6 m/s or >) were the 5 m walk test (comfortable pace); the BBS and the 5 m walk test (maximum pace); whereas in the slow group (0.3 m/s or <) the 3 most responsive measures were the BBS, the BI and the STREAM. Walking speed is an important outcome for orthotic studies as it enables the researchers to determine the impact on mobility in every day life, for example in America subjects need to attain a walking speed of at least 0.71 m/s to cross the road safely⁵⁷. It is worthwhile discussing two other clinical measures of mobility, the Rivermead Mobility Index⁵⁸ and the Modified Rivermead Mobility Index (MRMI)⁵⁹. The RMI was developed to measure disability related to mobility; it comprises 14 questions and one direct observation covering a range of activities such as turning over in bed to running; 10 out of 15 are relevant to orthotic intervention. It is scored on a 0 (unable) to 1 (able) scale for a total score of 15 points; 4 of the 8 items are relevant for orthotic intervention. Hsieh and colleagues⁶⁰ have established its' validity and sensitivity over time in the stroke population; it is worth noting that there needs to be a change of at least 3 points to show change exceeding measurement error. Lennon & Johnson⁵⁹ identified that the RMI failed to be sensitive to small changes that are clinically relevant during the patient's recovery following acute stroke; they therefore reduced the number of items from 15 to 8 and extended the scoring system to a 6 point scale for each item. The MRMI relies on observation of all 8 items, as this gives the therapists an indication of how the patient is performing the activities,

which is useful for treatment planning. There needs to be a difference of more than 4.5 points in order to detect change exceeding measurement error; 4 of the 8 items are relevant for orthotic intervention. With regard to the upper limb post stroke, the Action Research Arm test (ARA) was used in 6 out of 14 RCTs' in a meta analysis by Hirako⁶¹. This test contains 19 items grouped into 4 categories: grasp, grip, pinch and gross movement; there needs to be a change of 5.7 points out of 57 in order to exceed measurement error. The test takes about 8 minutes to administer (Finch and colleagues, p.74)³.

The clinician and researcher need to select the most appropriate test from a range of tools on offer. In order to do this, it is helpful to compare outcome measures in terms of their individual items before making this choice⁶². For orthotic intervention studies, functional activities related to balance could be standing up and sitting down, and transfers; activities related to mobility could be walking indoors, walking outdoors, and stair climbing, activities for the upper limb could be related to the grasp and manipulation of objects, and the integration of the affected upper limb into everyday activities. It would also be important to document any change in the level of assistance required to perform activities or the need to use walking aids, as these changes are clinically meaningful for the patient's independence and the care-giver's role.

SUGGESTIONS FOR A CORE BATTERY OF OUTCOME MEASURES

It is not possible to recommend specific outcome measures, which are appropriate to all studies, however it is possible to make a list of suggestions. Some suggestions from this review and the expert panel at this consensus conference on Orthotic Management in People following Stroke are presented in Table 5.

Outcome measure	Measurement
Impairment	
Muscle activation	EMG electrodes
Movement analysis	Joint motion, co-ordination of joints/segments
Kinetic analysis	Forces, static/dynamic balance
Motricity Index ⁶³	Muscle power
Dynamometry	Torque around a joint
Berg Balance Score ^{3,64}	Balance during activity
Functional Reach ³	Balance during activity
Step test ⁵⁶	Single Limb Stance balance
Visual Analogue Scales	Pain/Comfort
Chedoke McMaster ⁴⁸	Composite impairment
Instrumented walkways	Tempo-spatial gait parameters
In-shoe pressure systems	Foot forces during functional activity
Function	
Action Research Arm Test ^{3,65}	Functional use of the upper limb
Box & Block test ⁶³	Manual Dexterity
Frenchay Arm test ⁶⁶	Arm function
5 meter walk ⁵⁴	Gait velocity
10 meter walk ⁴⁹	Gait velocity
6 minute walk ⁴⁹	Walking endurance
Timed get up & go ³	
Functional Independence Measure ³	Movement & Function
Fugl-Meyer Assessment ^{73,67,68}	
Motor Assessment Scale ⁶⁹	
Functional Mobility Scale	Mobility
Modified Rivermead Mobility Index ⁵⁹	
Rivermead Mobility Index ⁵⁸	
Other	
Canadian Occupational Performance Measure ⁷⁰	
Falls Efficacy Scale ⁷¹	
Goal Attainment Scaling ⁷²	

Table 5: Suggested Outcome Measures to consider for use in studies of orthotic intervention after stroke

Note: Efficiency of Assistive Technology and Services (EATS): recommendations for outcome tools related to assistive technology and service not specific to stroke can be found at www.utoronto.ca/atrc/reference.atoutcomes/ATOTools.html

It would seem sensible to have a collection of outcome measures on which researchers and clinicians can draw, for example orthotic intervention may be effective at improving weight-bearing through the paretic lower limb, so this needs to be measured; however to date there is little evidence to suggest that improving weight transference to the hemiplegic side improves gait directly⁷³. Therefore this improvement at the impairment level to be meaningful to the patient following stroke should be reflected at the level of activity, and possibly participation⁶². Just as studies should also assess the impact of an impairment focused approach on meaningful, functional activity, adopting a holistic approach does not preclude a focus on the impact of pathology and impairment on activity and participation⁷⁴. Indeed some improvements in postural control may be transferable to other aspects of functional activity⁷⁵. Choosing of measures will also need to consider the need for different measures with patients with different levels of severity as well as at different stages of the rehabilitation process i.e. no one study can be expected to cover all aspects from physiology to patient satisfaction.

A further point for consideration when using functional outcome measures, is that both total scores and scores for individual items need to be presented in research reports, as these scores combine several types of functional activities that are not always relevant to the aim of the orthotic intervention. Therefore, the total score for different patients does not carry the same meaning in terms of the magnitude of difference for items specifically related to orthotic intervention. It would be important to establish a consensus on a battery of outcome measures that could be used at the level of both impairment and disability. This would facilitate comparisons of outcomes between rehabilitation settings in different centres and indeed different countries. By ensuring comparability between research studies, this would also enable the use of meta-analysis to gain added value from available data whether or not research groups plan studies together in advance.

A last but very important point is to consider using outcome measures that capture the type of changes that have an impact on the person's experience of life after stroke. Pound and colleagues⁷⁶ interviewed 40 people who were living in the community at least 10 months post stroke in order to explore their subjective accounts of the consequences of stroke. The following main themes were reported: difficulty leaving the house, unhappiness, difficulty with housework, leisure activities, walking, talking, washing and bathing, relationships and confusion/memory problems. Orthotic intervention has the potential to impact in particular on four of these themes: the ability to leave the house, to do housework, to take part in leisure activities, and to walking. Difficulty leaving the house can involve managing stairs, climbing kerbs, and getting on/off buses. Doing housework would involve being able to stand without help, balance and the use of the affected upper limb. Improved mobility could be measured in terms of taking public transport, going outdoors for a stroll, shopping, and crossing the road.

Participants in the study conducted by Pound and colleagues⁷⁶ also discussed falls and fear of falling, which could lead to a loss of confidence, and also isolation and loneliness. Orthotic intervention may be particularly relevant in preventing falls by improving ankle stability and reducing the likelihood of tripping; recent papers by Hellstrom and colleagues^{71,77} suggest that self-reported confidence in task performance using a measure such as the Falls Efficacy Scale (FES) may be a valuable outcome measure which also impacts on the person's lifestyle. The FES assesses the person's confidence in 13 items common in everyday life with each item scored on an 11 point visual scale from 0 to 10 for a maximum score of 130. It only takes 3 to 5 minutes to complete. Aiming to reduce falls or improve confidence in mobility tasks through orthotic intervention would not only meet the requirements of recent government framework documents within the UK (National Service Framework for Older People)⁷⁸ but would also take account of issues that are patient-centred⁷⁶. Professional societies in the UK have recently published two reviews in the area of falls prevention, which provide advice on outcome selection in this area^{79,80}.

It is of note that outcome measures of domestic ability and participation were not included in any of the studies reviewed in this paper. In summary, when conducting further studies of orthotic intervention it would be essential to use a range of outcome measures relevant to impairment, activity and participation; these would need to involve the patient, the care givers and the other members of the multi-disciplinary team. Any outcome tools chosen should match the aim of the orthotic intervention, and demonstrate the key measurement attributes of validity, reliability, and sensitivity.

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CURRENT RESEARCH IN ORTHOTICS (R18)

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This article provides an overview of current orthotic research, focussing particularly on the management of patients who have suffered stroke. By learning lessons from the past and from other areas of health care research a framework for the future direction of orthotic research is proposed.

Orthoses are designed to overcome specific biomechanical problems to achieve defined clinical treatment goals. Finding plausible solutions to biomechanical problems is the task of not only orthotists but also many mechanical and bio-engineers. This *technological research* involves designing new devices or experimenting with new materials, components or manufacturing methods to develop orthoses that are more efficacious, aesthetically pleasing or lighter than existing designs. However, solving biomechanical problems does not necessarily ensure that the treatment goals are achieved; neither does tell us whether the orthosis will be more effective than other interventions in achieving the same goals. To answer these questions we need *clinical research* methodology.

One broad definition of research is 'some systematic means of gathering information to answer questions'¹. Fundamental issues are therefore: what questions are being asked in orthotic research? and how are the answers being investigated? This paper reviews the questions commonly being asked in orthotic research with respect to stroke and discusses to what extent the research methodologies being employed are able to provide answers.

SEARCH STRATEGY

The search aimed to identify the spectrum of orthotic research and hence a strategy with high sensitivity was employed. Synthesised or secondary sources of evidence included health technology appraisals, in the form of national or professional guidelines, and health technology assessments such as systematic reviews. Evidence from primary studies was included if the paper described clinical trials of an orthosis for stroke patients versus another or no orthosis. The search included the databases of The Cochrane Library (2003 Issue 2), Medline and AMED (both WinSpis 4.0), and also hand searching the lists produced by RECAL Information Service for other reviewers. The UK National Research Register (2003 Issue 3) was searched to review any recent or ongoing research.

SEARCH RESULTS

The most common questions in orthotic research for stroke patients ask whether one type of orthosis is superior in achieving an outcome of health benefit over another orthosis, another treatment or no intervention. The World Health Organisation's International Classification of Functioning, Disability and Health (ICF) enables us to distinguish between outcomes in terms of impairments of

the structure of the body, such as correcting or preventing deformities; or in overcoming activity limitations such as standing, transferring or walking; or in participation such as getting back to work or some favourite pastime². Outcomes of orthotic management may be defined in each or all of these dimensions.

The commonly reported research questions for the management of stroke are listed in the table below with the dimension of the ICF they address.

Research question	ICF dimension
Can an orthosis prevent shoulder subluxation and pain?	Impairment
Can orthoses prevent fixed upper or lower limb deformities?	Impairment
Does an orthosis improve gait efficiency?	Activity
Does an orthosis improve functional performance?	Activity
Do wrist hand orthoses improve dexterity?	Activity
Are plastic AFOs better than metal AFOs?	Impairment / Activity
Is FES more effective than orthosis to improve function?	Activity
Is there an increased effect using orthoses with adjuvant interventions?	Impairment / Activity
What is the patient's perception and satisfaction of their health care	Quality of life
Can the design of orthoses be improved?	Technical

Outside of the ICF framework are the perceptions of the patient of their quality of life and satisfaction with their health care. In a case series existing users of hinged AFOs reported being satisfied with their orthosis³. Although the findings have little utility without a reference group, it is important to consider and measure when possible the psychosocial impact of orthotic interventions. Also outside the ICF are the technological research issues reviewed by Chu⁴. In order to examine the ways in which researchers have attempted to answer these questions the types of studies were categorised into the levels of evidence. For the purpose of this paper it was not vital to estimate the exact numbers for each type of study but more important to identify the fact that most published studies of orthotic research are low in the hierarchy of levels of evidence. A summary of the types of studies were identified is shown in the following table.

Type of study	LoE	No.
Guidelines		1
Systematic reviews (<i>Cochrane protocols</i>)	I	5 (2)
Randomised Controlled Trials with definitive results	IIa	-
Randomised Controlled Trials with non-definitive results	IIb	3
Cohort studies	III	-
Case-control studies	IV	-
Cross sectional studies (including within-subject comparisons)	V	> 100
Case reports	VI	> 20
Expert opinion (quoted in guidelines)	VII	1

One randomised controlled trial (RCT) used a 2 x 2 factorial design to assess the effectiveness of tibial nerve blocking in addition to or without an orthosis. This study recruited 60 patients and the outcomes of interest were measured at 6 and 15 weeks. Findings reported in two papers noting no differences between orthosis and non-orthosis groups in terms of impairment or walking ability⁵. Two RCTs examined the role of supportive orthoses to prevent shoulder pain with non-definitive results. The remainder of studies used within-subject comparison methodology and consequently the duration of follow up has been limited. Many of these studies continue to examine the immediate effects of different orthosis on gait using motion analysis laboratories.

The National Clinical Guidelines for Stroke⁶ produced by the Royal College of Physicians in the UK (RCP) have appraised the evidence for lower limb orthoses concluding that (*with the grade of recommendation A, B or C*):

‘Ankle-foot orthoses are of benefit for some patients (B)

If an ankle-foot orthosis is supplied, it should be individually fitted (C)’

(see 9.6.3 Guidelines *e* and *f*)

Support for the benefit of AFOs, albeit only for some patients, is referenced to a paper by Corcoran et al from 1970. This was not an RCT but a within-subject comparison study with 15 patients. Gait was shown to be more efficient with either a metal or plastic orthosis than with no orthosis measured using walking speed and oxygen cost, but the difference between them was not statistically or clinically significant. The RCP guidance notes that the evidence for ankle-foot orthoses is inconsistent citing the non-definitive results of the RCT by Beckerman et al. The effectiveness of

shoulder supports to prevent pain has not been definitively demonstrated. Protocols for two Cochrane reviews were identified: one looking broadly at the orthotic management of upper and lower limbs following stroke or other non-progressive causes of spasticity, and another looking specifically at supportive devices to prevent shoulder subluxation after stroke.

Functional electric stimulation (FES) is not by definition an orthosis. However FES has been evaluated as an alternative to orthoses such as AFOs to overcome activity limitations. Research using FES has evolved over several years from methodology using small case series, within subject comparisons with no treatment as a control, to current and ongoing RCTs comparing FES with standard treatment using AFOs. There has also been consideration of the econometrics of the technology.

An analysis of routinely collected data by Teasell et al showed that users of AFOs at discharge from their institution scored lower on a range of health status measures than patients who did not use an AFO⁷. Whilst the utility of this retrospective study is difficult to interpret, because the groups are identified by an intervention rather than an outcome, it suggests perhaps that it may be possible to identify patients with the potential to benefit from orthoses using standardised health status measures. This sort of study would of course be better conducted prospectively.

DISCUSSION

Despite technological development, on the whole there remains a dearth of unbiased clinical research regarding the effectiveness of orthotic intervention for stroke with most studies reporting small numbers of subjects, short follow up periods and often lacking an adequate control for comparison. The poor methodological basis for much of the clinical evidence leaves us prone to errors in interpretation: either (i) believing there are benefits from orthoses when in fact there are not (Type I), or (ii) rejecting using orthoses which may actually confer benefits (Type II)⁸. First let us consider the quality of the questions being asked. Properly constructed research questions describe exactly who is being studied, what will be done to them and what outcomes are important.

Asking the right questions

Interventions

A key problem with current orthotic research is the inconsistency in terminology used to describe interventions, for example the use of trade rather than generic names or ambiguous terms such as ‘dynamic’. A photo or diagram often helps but clear nomenclature using the ISO system describing which segments of the body are encompassed is essential⁹. In addition it is helpful to have an indication of the biomechanical effect of the orthosis. For example ‘plantarflexion and dorsiflexion prevented’ for a rigid AFO; or ‘plantarflexion prevented and dorsiflexion permitted’ for a hinged AFO with a plantarflexion stop; or ‘plantarflexion prevented and dorsiflexion assisted’ when there is some ‘active’ force applied by the orthosis to assist dorsiflexion.

Outcomes

Many of the studies have used special equipment such as motion analysis systems to measure outcomes. Selecting simple outcomes that do not require special technology would enable less expensive and therefore larger and studies to be conducted. These simple outcomes should be defined for the different dimensions of the ICF. Duration of follow up is a key detail in rehabilitation research, as some functional recovery would be expected without intervention. The primary outcomes of orthotic clinical research in stroke rehabilitation might be better measured after some months rather than days or weeks. The immediate effects, or biomechanical efficacy, of orthoses are understood but it is their effectiveness in the longer term that remains to be established.

Subjects

Having defined the intervention and outcomes appropriately the remaining issue is to adequately describe the patients who may benefit. The severity of disability of survivors of stroke varies considerably and in clinical trials it is important that we ensure we are comparing like with like. The study by Teasall et al. suggests that patients who use AFOs are likely to be more disabled than those who do not. Clearly some valid and reliable measure of the severity of disability is essential to ensure patients receiving the experimental and control interventions are comparable and that findings from studies can be generalised to other people. Some researchers have distinguished between patients in the recovery period as either earlier than or after 6 months since the stroke; although this may be an arbitrary cut point it does permit generalisation. The severity of disability may be best measured using a standardised health status measure.

Equipoise

A final point on asking good research questions regards the 'uncertainty principle'. If we honestly do not know which form of treatment is better then we can ethically randomise patients to either treatment schedule. Consensual equipoise among the clinical community is required rather than necessarily the uncertainty of individuals¹⁰. In orthotic research it is more often the case that opinions become polarised over differing treatment regimens. Then it can be difficult to progress the consensus opinion towards the need for a scientific experiment despite a lack of evidence. The research question must be perceived as relevant to clinicians to ensure interest in the study, adequate recruitment and compliance with treatment schedules.

Getting the right answers

The next issue to consider to what extent the methodologies being utilised by researchers are able to answer the questions posed. The hierarchy of the 'levels of evidence and grades of recommendation' as a system for ranking studies based on their methodological rigour¹¹ was used in the RCP guidelines. However this framework does not provide only a limited analysis of the quality of the evidence available and how it may be improved upon. Therefore it may also

be useful to consider the *phases* of clinical trials commonly used in pharmaceutical research¹².

Phases of clinical trials

Trials at each phase have a different purpose and set out to answer different questions. In Phase I small numbers of subjects usually all get the intervention, perhaps with different intensities or regimens, and are closely followed to determine if there is indeed a safely derived health benefit. In Phase II there is some comparison with current standard treatment or placebo to gauge the size of any treatment effect. Effectiveness is properly tested in Phase III with a large enough number of subjects to measure whether any clinically important difference occurs using the intervention, assessed *a priori* with a sample size calculation. Put simply, Phase I and II clinical trials confirm efficacy and gauge the size of treatment effect under closely controlled conditions and Phase III trials confirm the effectiveness. Phase IV studies monitor the effectiveness of interventions once they are licensed and marketed and any side effects. Even a cursory review of the literature suggests that most orthotic research is in Phases I and II, or perhaps at Phase IV but without necessarily progressing through Phase III.

Efficacy and effectiveness

Some research confirms how an orthosis works, its efficacy. Instrumented kinematics and kinetic motion analysis has been used to show how orthoses change the forces acting around lower limb joints during gait and hence the gait pattern. This we can regard as Phase I as all the patients are treated the same and are investigated with measures usually unavailable to most clinicians. There are reports of orthotic clinical trials where patients receive different interventions either randomly or sequentially but the study populations are so small that we cannot rely on the results. Sadly this is typical of trials in orthotic research as well as many other areas of health care although this research may be useful if considered as Phase II, but it must be followed with a phase III study to test its effectiveness. It is well known that small trials can overestimate treatment effects and are often misleading, as pointed out by Pocock (p134)¹³:

'Until a greater effort is made to achieve larger numbers in all types of clinical trial, much published clinical research remains essentially futile since it lacks the resources to answer the clinical questions being posed.'

Some researchers have elected to use patients as their own controls in crossover trials, for example the 1970 study by Corcoran et al. evaluating plastic and metal AFOs. This method may be useful for efficacy studies, for example the immediate effects of different orthoses on gait patterns, but will not usually tell us whether there is any benefit over time, such as a motor learning effect or prevention of deformity. Indeed, the influence of recovery during rehabilitation that may not be directly associated with the treatment regimen implicitly demands longitudinal prospective study. To evaluate whether there is a difference in outcome from different regimens using one orthosis over another or no orthoses groups of patients probably need to be followed up

over periods of several months. Sadly in orthotic research this has not been the case; one of the most recent orthotic research papers to be published compares plastic and metal AFOs in a within-subject comparison of 12 patients¹⁴.

Perhaps unsurprisingly, what is concluded and recommended from this review is evolution towards larger clinical trials with longer follow up periods. Small local trials may still be beneficial as preliminary or pilot studies, and especially suited to postgraduate theses, but risk wasting patient's time and valuable resources when repeating earlier work. Adapting the framework of phases in clinical trials for orthotics may orientate researchers towards where their efforts would be best targeted.

THE EVOLVING PARADIGM OF ORTHOTIC RESEARCH

There are many reasons for the poor design of current and past clinical trials in orthotics.

Research capacity in orthotics

The situation may in part be due to the practical nature of orthotics and orthotists and relatively recent development of an academic profession. Necessarily, given the everyday duties of an orthotist, there has been a strong practical and bioengineering influence rather than clinical epidemiology in orthotics. This is evident in the number of reports of innovative new designs of orthoses often in conjunction with a commercial marketing strategy. There are frequent reports of new equipment to assess interface pressures or gait arising out of the field of mechanical engineering. Technical innovations are constantly flourishing but there is almost no comprehensive clinical evaluation or epidemiological study of the magnitude of health benefit. In the UK the Department of Health has recognised the need to invest in the research capacity of the workforce and has begun creating research career opportunities for members of the allied health professions. In North America the Journal of Prosthetics and Orthotics published a series of articles between 1995 and 1996 emphasising the need for research skills to be included in basic training. An excellent history of the evolution of science in orthotics and prosthetics was also published in the journal¹⁵.

Technology assessment

There are some other cultural reasons for the lack of health technology assessment in orthotics. One of the main drivers for medical research is the need for commercial organisations to demonstrate the effectiveness of an intervention before marketing new technologies. In the UK this is regulated by the Medicines and Healthcare Products Regulatory Agency, conforming to the legislation in the European Union, and in the USA by the Food and Drug Administration. Similar agencies will exist in other countries.

Orthoses evade this formal process of evaluation because they are usually custom-made. Perhaps the more robust evaluation of FES technology is driven by such requirements?

There are other areas of health care with similar mixes of art and science such as surgery and other hands-on therapies which face similar difficulties in their evaluation. Some may contend that in these situations it is not possible to adequately control the interventions as each is unique in its construction or application. However we would argue that this merely represents the real world scenario in which care is delivered and is therefore actually an important feature of any trial. The setting is further complicated by the fact that the many practicing orthotists are employed by the companies that are making and selling the products. Some formal evaluation of commonly prescribed items, such as AFOs, and the influence of commercial bias should be established and monitored by the country appropriate regulatory agency.

The need for a critical approach

Some clinicians prefer to continue their orthotic practices based solely on tradition or their beliefs and perceive research as unnecessary. One common rebuttal is that patients are all so different that one cannot generalise from one to another. Orthotics is not exceptional in this respect; indeed medicine itself has only embraced the scientific method gradually over the past few hundred years and the first randomised trial with concealed allocation to treatment was conducted as recently as 1948. Bradford Hill, one of the researchers who designed this study, wrote eloquently of how human variability makes clinical trials and statistical methods essential¹⁶. Before these landmark events there were numerous examples of clinicians regaling the success of treatments as broad as bloodletting and spa-bathing using uncontrolled experiments, some of these are scholarly recounted by Trohler¹⁷. In all areas of medicine there are those who continue to perceive research and the evidence-based practice lobby as a threat to their clinical art and autonomy rather than as the natural progress of science.

There have been changes in orthotic management brought about by detailed observation in the absence of clinical trials. For example, despite the array of orthotic devices designed to meet the biomechanical objectives for unloading and abducting the child's hip affected by Perthes disease, these are almost never used today because they do not have any beneficial impact on the condition and may in fact have caused psychosocial harm. We might reflect on this and the answer may seem obvious to us now but one wonders how many of the orthoses we prescribe today will stand the test over time. So, where possible at least, we should be critical of our clinical practice in orthotics and seize on our uncertainty of whether particular applications of orthoses are effective as opportunities for clinical trials. Whilst blinding patients to orthotic management is not possible, it may be possible in some circumstances to blind those evaluating outcomes (single blind) and execute all other important design features such as concealed random allocation that are crucial to overcome biases. For some outcomes such as side-effects research observational methods may be more appropriate. Indeed, side effects research in orthotics may identify the underlying meaning of the RCP guideline that AFOs should be individually fitted.

If more advanced clinical trials are considered necessary for orthotics then beginning one of the most common disabling conditions in adults should help prevent recruitment being a problem. That is of course providing a framework for multi-centre study can be established. Identifying the most important research questions should be a priority. Identifying the stakeholders in orthotic research will help rate of change in the evolution of research in orthotics. The accomplishment of large trials is more likely to succeed with the collaboration of those who are experienced in the field. In the UK for instance the MRC Clinical Trials Unit Division without Portfolio is particularly interested to collaborate in establishing trials in areas of medicine where there are 'important questions to address, but no current infrastructure to support trials or strong tradition of clinical trials.

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